

EXHIBIT

B

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 AT CHARLESTON

4
5 IN RE: ETHICON, INC., Master File No.
6 PELVIC REPAIR SYSTEM PRODUCTS 2:12-MD-02327
7 LIABILITY LITIGATION MDL 2327

8 -----

9 THIS DOCUMENT RELATES TO CASE
10 CONSOLIDATION:

11 Terreski Mullins, et al., v.

12 Ethicon, Inc., et al.

13 Case No. 2:12-CV-02952

14 -----

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16

17 DEPOSITION OF

18 VLADIMIR IAKOVLEV, M.D.

19

20 * * * *

21 HIGHLY CONFIDENTIAL PORTION

22 * * * *

23

24 September 14, 2015

25 9:00 a.m. - 5:05 p.m.

1 Deposition of VLADIMIR IAKOVLEV, M.D.,
2 a witness herein, called for examination by counsel
3 for the Defense, in the above-mentioned matter, the
4 witness having been affirmed, taken at the law
5 offices of Siskinds LLP, 100 Lombard Street,
6 Toronto, Ontario, commencing at 9:03 a.m. on
7 Friday, September 11, 2015, and the proceedings
8 taken down by Stenotype and transcribed by
9 JUDITH M. CAPUTO, RPR, CSR, CRR.

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1 A P P E A R A N C E S:

2

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1 I N D E X

2

3 WITNESS: VLADIMIR IAKOVLEV

4 PAGE

5 DIRECT EXAMINATION BY MR. THOMAS.....5

6 CROSS-EXAMINATION BY MR. ORENT.....296

7 **Highly Confidential Portion noted on page 40**

8

9

10 I N D E X

11 NUMBER/DESCRIPTION PAGE NO.

12 NO. 1: Expert Report of Dr. Iakovlev in the 5

13 Mullins consolidated cases.

14 NO. 2: Supplemental Expert Report of 5

15 Dr. Iakovlev in the Mullins consolidated cases.

16 NO. 3: Notice of Deposition of Dr. Iakovlev. 5

17 NO. 4: Thumb drive. 5

18 NO. 5: Study Entitled, "Safety Considerations 259

19 for synthetic sling surgery."

20 NO. 6: Article entitled, "Degradation of 271

21 polypropylene in vivo: A microscopic analysis

22 of meshes explanted from patients."

23 Authored by Vladimir Iakovlev, et al.

24

25 -- NOTE: Exhibit 4 was retained by Mr. Thomas.

Vladimir Iakovlev, M.D.

1 EXHIBIT NO. 1: Expert Report of
2 Dr. Vladimir Iakovlev in the Mullins
3 consolidated cases.
4 EXHIBIT NO. 2: Supplemental Expert
5 Report of Dr. Vladimir Iakovlev in the
6 Mullins consolidated cases.
7 EXHIBIT NO. 3: Notice of Deposition of
8 Dr. Vladimir Iakovlev.
9 EXHIBIT NO. 4: Thumb drive.

10

11 Whereupon,

12

VLADIMIR IAKOVLEV, M.D.,

13 called for examination by counsel for Defendant
14 and having been affirmed by me, was examined and
15 testified as follows:

16

DIRECT EXAMINATION BY MR. THOMAS:

17

Q. Good morning, Doctor.

18

We've met before. My name is David

19 Thomas. I'm going to ask you a number of questions
20 about your expert witness opinion in the Mullins
21 case pending in the MDL in West Virginia; fair
22 enough?

23

A. Yes.

24

Q. I'm going to hand you what I've

25 marked as Exhibits 1 and 2 and ask you if Exhibit

1 Nos. 1 and 2 are the expert reports that you
2 prepared in the Mullins case.

3 A. Yes, that's correct. This one is
4 on the left, the thicker one, is a combination of
5 several patients and this one on the right, Exhibit
6 No. 2, is a supplemental set of figures
7 specifically from the specimen of Ms. Mullins.

8 Q. And Exhibits No. 1 and 2 represent
9 the complete opinions you're prepared to give in
10 this case; is that fair?

11 A. That's correct.

12 Q. I show you now what's been marked
13 as deposition Exhibit No. 3. That's a Notice of
14 Deposition in this case.

15 A. Yes, I do see it.

16 Q. Have you seen that before today?

17 A. Yes, I did.

18 Q. As a part of Exhibit 3, there's a
19 request attached to it that you produce documents
20 in response to that.

21 A. There are 27 requests. Yes, I've
22 seen that.

23 Q. Did you review those requests?

24 A. Yes, I did.

25 Q. Did you attempt to collect the

1 information contained in those requests and produce
2 it to me today?

3 A. Yes, I gathered all what I could
4 on the thumb drive.

5 Q. And counsel has given me today
6 what I've marked as Exhibit No. 4, which is a thumb
7 drive. Is this the thumb drive that you just
8 described where you attempted to load all of the
9 documents responsive to the Notice of Deposition
10 that you could find to put on the thumb drive?

11 A. That is correct.

12 MR. ORENT: At this point I want to
13 place an objection and notification. We did file a
14 written objection so subject to those written
15 objections that material has been produced.

16 BY MR. THOMAS:

17 Q. To save the time of going through
18 the notice or the thumb drive for right now, can
19 you recall any documents responsive to the Notice
20 of Deposition that you did not include on the thumb
21 drive?

22 A. Well, the communication with
23 lawyers I didn't put.

24 Q. Okay.

25 A. The rest, I think I included

1 everything I had pertinent to this case.

2 MR. ORENT: Just to clarify though
3 again, the communication, I believe, was outside of
4 the three areas specified on Number 27.

5 MR. THOMAS: I'm sorry, I did not hear
6 you.

7 MR. ORENT: Under the federal rules
8 your request Number 27, to make the federal rule
9 recognizing the privilege existing between expert
10 and attorneys.

11 With the exception of the three areas
12 that you requested, I believe there were no
13 responsive communications specifically to those
14 three areas.

15 I believe other communications exist
16 that are not discoverable, and that's what the
17 doctor is referring to.

18 MR. THOMAS: Okay.

19 MR. ORENT: I don't believe he withheld
20 anything responsive to the request as written.

21 BY MR. THOMAS:

22 Q. Doctor, you've given depositions
23 before in the Ethicon MDL, correct?

24 A. That is correct.

25 Q. You've testified in connection

1 with the Bellew case?

2 A. Yes, I did.

3 Q. And you've testified in connection
4 with the Huskey and Edwards cases, correct?

5 A. That is correct.

6 Q. And in those depositions you
7 testified to a methodology that you used to collect
8 specimens, create histopathological slides where
9 appropriate and review those slides.

10 Did you follow the same process in the
11 Mullins case that you followed in the Bellew and
12 Huskey Edwards cases?

13 A. The process is standard. It's not
14 specifically for medical-legal cases or mesh cases.
15 It's a standard histology protocols in a diagnostic
16 pathology lab, so I don't change it. I follow them
17 for each specimen regardless if it's medical-legal
18 or a regular hospital patient.

19 Q. Doctor, my question really meant
20 to eliminate re asking all those questions that
21 were asked in Huskey, Edwards and Bellew.

22 And if we can confirm that you followed
23 the same procedures in the Mullins case that you
24 followed in the prior depositions where you were
25 asked about your procedures then I'm not going to

1 go over that again. Can we confirm that you
2 followed the same steps?

3 A. Yes, I can confirm that.

4 Q. Doctor, what is a neuropathologist?

5 A. Neuropathologist?

6 Q. Yes.

7 A. Neuropathologist is a surgical
8 pathologist who is specializing in examining brain
9 tissue or spinal cord. Sometimes it's the
10 subspecialty people do just neuropathology;
11 sometimes there is cross-coverage.

12 In our institution we have a
13 neuropathologist but it's only one. Sometimes he
14 goes away on meetings, so we cover neuropathology.

15 Q. Are you a neuropathologist?

16 A. I'm cross-covering neuropathology
17 when he is away but I have not specialized in
18 neuropathology.

19 Q. Are you board certified in
20 neuropathology?

21 A. No, and you don't have to be board
22 certified in neuropathology because surgical
23 pathology includes neuropathology.

24 I mean, you can sub specialize further
25 down, but it depends on specific institution.

1 Because some institutions have a large number of
2 specialized cases and some institutions they cover
3 broad range.

4 Q. You said you had a
5 neuropathologist at St. Michael's?

6 A. Yes, we do.

7 Q. What is the person's name?

8 A. Dr. David Munoz.

9 Q. Is that the only neuropathologist
10 at St. Michael's?

11 A. Right now, yes.

12 Q. Did you consult with Doctor --
13 what's his last name?

14 A. Munoz.

15 Q. M-U-N-O-Z?

16 A. Yes.

17 Q. Did you consult with Dr. Munoz in
18 connection with any of the opinions that you've
19 given in this case?

20 A. No.

21 Q. Did you consult with any
22 neuropathologist in connection with the opinions
23 you've given in this case?

24 A. We're not talking about brain
25 tumors; we're talking about sub tissue

1 transvaginal. I mean, why would I consult a
2 neuropathologist?

3 Q. Just a simple yes or no question?

4 A. No, I didn't. There was no
5 purpose.

6 Q. Did you consult any neuropathology
7 textbooks in connection with your opinions in this
8 case?

9 A. Specifically just recently?

10 Q. Any time during your work in this
11 case?

12 A. Not in this case. I opened and
13 read several neuropathology books when I was doing
14 research in meshes. It's not just neuropathology
15 books, I mean, neuropathology is described in
16 general surgical pathology books. Because I've
17 been in this field for three years.

18 Q. I understand. Just specific
19 questions, we'll get done quicker if you answer
20 "yes" or "no", if you can, and I'm not trying to
21 pin you down.

22 Is it your belief that neuropathology
23 has no role in understanding the presence of nerves
24 in the pelvic floor?

25 MR. ORENT: Objection to form.

1 THE WITNESS: Yeah, actually the form
2 of the question is quite bizarre.

3 Because neuropathology is part of
4 surgical pathology. So I'm a surgical pathologist
5 I'm examining -- yes, there is a field of
6 neuropathology when you specialize in that.

7 If you take a combination of peripheral
8 nerves as part of neuropathology, then I can say
9 yes, there is a part of neuropathology. But as I
10 said, it's still within surgical pathology.

11 This separation is somewhat artificial.
12 You probably don't understand exactly how such
13 specialization works. Probably that's where it's
14 coming from.

15 BY MR. THOMAS:

16 Q. Perhaps. Do you know a Kenneth
17 Aldape, A-L-D-A-P-E?

18 A. No.

19 Q. Lorraine Kalia, K-A-L-I-A?

20 A. No.

21 Q. Julia Keith?

22 A. No.

23 Q. Tim Rasmus Kiehl, K-I-E-H-L?

24 A. The names might be similar. I
25 mean, a couple of those names are the same as a

1 couple of neuropathologists in Toronto, I believe,
2 but I don't know their first names.

3 Q. My information is these
4 neuropathologists are affiliated with the
5 University of Toronto.

6 A. Yes, so Dr. Kiehl is practicing at
7 UHN and I think there was another name that also
8 practices at UHN. It's a different institution.
9 The U of T affiliated hospital is called UHN.

10 Q. There's special neuropathology
11 journals, aren't there?

12 A. Yes, there are.

13 Q. Do you subscribe to any?

14 A. No.

15 Q. So fair to say you don't serve on
16 the editorial board of any neuropathology journals,
17 true?

18 A. No, that's true.

19 Q. Is there any reason for you to
20 consult with a neuropathologist to understand how
21 nerves function in the pelvic floor?

22 A. Not really. The only reason I
23 would go to a neuropathologist when there is
24 something I don't know and I cannot find answers in
25 regular books, something which comes from

1 experience. We are talking about basic function.

2 Q. In Canada, is there a board
3 certification for your position as anatomical
4 pathologist?

5 A. Yes, there is.

6 Q. Is there a board certification for
7 neuropathologists?

8 A. I'm not sure, but we are
9 practicing neuropathology with this anatomical
10 pathology certification.

11 Q. As far as you recall, you haven't
12 consulted with any neuropathologists in connection
13 with your work in this mesh litigation; fair?

14 MR. ORENT: Objection.

15 THE WITNESS: Not for this specific
16 case. Earlier, when I started research, I ask a
17 few questions which stain sometimes it was better
18 to use when there is pathology of nerves.

19 BY MR. THOMAS:

20 Q. Who did you ask?

21 A. Dr. Munoz, but I think it was even
22 before the litigation started.

23 Q. And what did you ask Dr. Munoz?

24 A. Which stains he was using, if he
25 was using something different that I was using.

1 Q. And what question did you ask him?
2 What stain do you use for what?

3 A. When we started our research in
4 meshes, the question was, if the nerve's ingrown.
5 So this is kind of basic question.

6 Q. Sorry, if the nerves what?

7 A. Grow into the mesh. So this was a
8 basic question. But then I was thinking, okay, so
9 I need to make sure that I'm not missing anything
10 and I started thinking of possible scenarios, how
11 nerves can be affected by the mesh.

12 Are they going atrophic, can they
13 disappear completely? And if they go atrophic, you
14 can see atrophy in the nerve with any stain,
15 because the area becomes empty, sort of ooze, the
16 Schwann cells disappear, their axons, this is a
17 basic knowledge.

18 And I ask him if he's using something
19 else, and he was using exactly what I was using.

20 Q. So is it fair to understand that
21 you confirmed with Dr. Munoz your choice of the
22 S100 stain for nerves?

23 A. No, that was not about the S100.

24 Q. What stain specifically was it
25 about?

1 A. If anything else he's using to
2 examine nerve atrophy or degeneration.

3 Q. And what were you using to analyze
4 that question?

5 A. Just locating H&E.

6 Q. And Dr. Munoz said that was what
7 he was using to analyze the same question?

8 A. He said that you can see it on
9 H&E, but there are a number of other stains to
10 examine for nerve atrophy.

11 Q. And what stains did he tell you
12 that you could use, other than H&E?

13 A. Well, you can see some of the
14 atrophy on S100 -- I don't remember exactly what he
15 said because it was three years ago, because now
16 what I remember it might be coming from different
17 sources, so from my own experience.

18 Q. Do you have a specific
19 recollection of talking to any neuropathologist who
20 gave you any information about how to conduct your
21 investigation into these meshes?

22 A. I don't understand your question.

23 Q. You've told me about conversation
24 you had with Dr. Munoz. Do you have a specific
25 recollection, you remember having any conversations

1 with any neuropathologists about how to conduct
2 your work in these cases?

3 A. Why would I?

4 Q. I'm just asking you if you did or
5 not?

6 A. No, I didn't.

7 Q. Thank you. Now, Exhibit No. 1 and
8 Exhibit No. 2 are your reports in this case; we
9 talked about that already. They contain a number
10 of images?

11 A. That's correct.

12 Q. Have you supplied copies of all
13 those images on this thumb drive?

14 A. No, because they're already
15 included in the report. I can produce them for you
16 separately.

17 Q. Do you have digital images of the
18 slides in this report?

19 A. Of course.

20 Q. But they're not on the thumb
21 drive?

22 A. No, because they're already in the
23 report.

24 Q. Do you have images of the tissue
25 samples that are contained in the report that are

1 not in the report?

2 A. But we took those images together
3 with your expert.

4 Q. I'm just asking you if you have
5 them?

6 A. I should have them, yeah.

7 Q. Okay?

8 A. Because we were taking them -- he
9 would take picture. I would take picture of the
10 same field.

11 Q. But there are images that you have
12 of the tissue samples that are contained in your
13 report that are not produced on this thumb drive,
14 correct?

15 MR. ORENT: Objection.

16 THE WITNESS: There should be. I was
17 not using them. I was just recording together with
18 your expert when I received the specimens.

19 BY MR. THOMAS:

20 Q. Okay. And if you go to -- let me
21 just ask this question.

22 What is the source of the images that
23 are contained in your report? Where did you get
24 them?

25 A. I took them.

1 Q. Okay. And from what tissue
2 samples did you take them?

3 A. From explanted TVT and
4 TVT-O meshes.

5 Q. How many TVT?

6 A. Oh, that I would have to check
7 with my records now. I don't remember now.

8 Q. And TVT-O?

9 A. It's there, but I don't remember
10 now.

11 Q. And the TVT and the TVT-O
12 specimens that are contained in your report are
13 that, are those specimens from the set of specimens
14 that you obtained from Dr. Klinge?

15 A. No. It's a combination of earlier
16 medical-legal cases, patients of St. Michael's
17 Hospital, and samples which came within this
18 consolidated trial.

19 The earlier cases came from different
20 law firms.

21 Q. Do you know what I'm referring to?
22 You talked about the Bellew case, the set of slides
23 that you received from Dr. Klinge, and Dr.
24 Kreutzer, 22 TVT and TVT-O samples?

25 A. My recollection is I was contacted

1 by Anderson Law and I'm not sure when -- I don't
2 remember exactly where the package came from, but
3 all my communication was with the Anderson Law.

4 Q. I understand that, Doctor, but in
5 the Bellew case you testified at length about a set
6 of 22 TVT and TVT-O samples that you had received
7 from Mr. Anderson that had previously been reviewed
8 by Dr. Kreutzer and by Doctor Klinge?

9 A. Kreutzer for sure; I'm not sure
10 about Doctor Klinge. There were no records, or
11 maybe there was records but I just don't remember
12 them.

13 I didn't contact specifically Doctor
14 Klinge, or he didn't contact me specifically about
15 these samples.

16 Q. Are the images of the TVT and the
17 TVT-O slides that are in your report in this case
18 from the same set of slides that Dr. Kreutzer
19 reviewed?

20 A. Some of them could be. Again, I
21 don't remember now. It would be difficult to trace
22 them back.

23 Q. Do you have somewhere a key that
24 shows whose tissue this is in the report?

25 A. In the report, the way the images

1 were saved during my work, they would be usually
2 saved in folders for specific expert report.

3 Q. Let's go to page 19 of your
4 report, please, Exhibit No. 1?

5 A. So if we open these images, I
6 specify if the image is coming from consolidated
7 trial cases, which I received just recently, or if
8 the images are of additional cases, and additional
9 I meant previous TVT and TVT-O cases which I
10 received during the course of my work on expert of
11 possible Bellew case and others.

12 Q. How many consolidated cases do you
13 have images for, individual plaintiffs?

14 A. Like four, three. Three, four.
15 Some specimens came as bare mesh, had difficulty
16 embedding -- well, we embedded them but there was
17 not much in there.

18 Q. I understand. I'm just trying to
19 understand what you're working from.

20 So you have three or four tissue
21 samples from plaintiffs in the consolidated cases,
22 correct?

23 A. That is correct.

24 Q. What kind of mesh is that?

25 A. TVT or TVT-O.

1 Q. Okay. And so in your report,
2 where you refer to images of consolidated cases, is
3 it fair to say that those images come from the
4 three to four tissue samples that you got from the
5 consolidated cases?

6 A. That's correct.

7 Q. If you go to page 21?

8 A. Yes.

9 Q. Page 21 identifies in Figure Set
10 1c, images of additional TVT cases; what does that
11 mean?

12 A. That means this image comes from
13 previous TVT and TVT-O cases, or cases I received
14 previously.

15 Q. Can you tell by looking at this
16 whether it's a medical-legal or whether it's
17 something that came through St. Michael's?

18 A. It would have to be sort of
19 picture matching. I would have to open the folders
20 which contain previous reports.

21 It all depends how the figure was
22 taken. If it was taken by older camera, it didn't
23 record the case number.

24 Now, for some newer cases the images
25 were scanned and when the scanner works, there is

1 embedded surgical number.

2 Because they're all spread within
3 almost three years, some of them can be traced;
4 some of them would be difficult to trace.

5 Q. Is it fair to understand that
6 looking at the report, where you identify images
7 from additional TVT cases, you're unable to tell me
8 from what case that image comes from?

9 MR. ORENT: Objection.

10 THE WITNESS: In some cases I can, and
11 some cases I cannot. I can tell that you all of
12 them came from TVT and TVT-O because I kept strict
13 records for that.

14 But I didn't keep strict records for
15 specific cases, at least at the beginning.

16 BY MR. THOMAS:

17 Q. Okay. In those places where you
18 can identify the patient, did you do so in your
19 report?

20 A. No.

21 Q. Why not?

22 A. But they are not in this trial --
23 and they may be confidential. And why would I?

24 Q. But there are images in this
25 report that don't have identifying information --

1 none of them have identifying information?

2 A. They have one single identifying
3 information which is important: TVT or TVT-O.
4 Everything else doesn't matter.

5 Q. But I can't take this, go into
6 your file and figure out where this slide is, can
7 I?

8 A. I'm telling you it's all TVT and
9 TVT-O. What else do you need to know?

10 Q. Am I able to take this thumb drive
11 and figure out which slide is which patient on
12 page 21?

13 MR. ORENT: Objection. I think what
14 the doctor is explaining is that these are all from
15 prior reports served on you.

16 THE WITNESS: Most of them are. You
17 can go to older reports and find them.

18 BY MR. THOMAS:

19 Q. Why didn't you say "from the
20 Edwards case" to tell us where it came from?

21 A. Why would I? I don't understand
22 the question. I mean, this is an opinion about TVT
23 and TVT-O.

24 I am not making an opinion about
25 Edwards or any other specific patient. I am giving

1 you opinion about TVT-O as a product.

2 Q. Do you maintain your sets of these
3 slides by individual plaintiff?

4 A. In some cases, yes. If there is a
5 generated report because that is a specific
6 plaintiff, I save them as separate folder.

7 But remember those 23 or 22 cases when
8 they came as a bulk and I did not produce any
9 specific reports for specific patients, individual
10 patients. They were all saved in one folder.

11 Q. Okay?

12 A. Which was just additional --
13 didn't keep record for that.

14 Q. Are the files on this thumb drive,
15 Exhibit 4, marked by individual plaintiff?

16 A. No. As I said, I didn't include
17 figures because they were included in the report
18 already.

19 If you want me to include these
20 specific figures, I can do that. But it will not
21 be possible to trace specific picture, specific
22 patient.

23 And that was not the purpose because
24 the purpose was to give an opinion about TVT-O or
25 TVT as a product, not to give opinion for specific

1 plaintiffs.

2 Q. Exhibit No. 2 is a supplemental --
3 micro photographs. You identify those as from the
4 specimen of Ms. Elizabeth Mullins?

5 A. That is correct.

6 Q. Is Elizabeth Mullins -- strike
7 that. Did you share this tissue with Ethicon?

8 A. Yes, I mailed it a week ago.

9 Q. Why did you identify this by
10 patient name and not identify the others in your
11 report by patient name?

12 A. Because it was a single case
13 specifically supplemented for one specific patient.

14 Q. So this is one of the three or
15 four TVT, TVT-O cases that you reviewed for
16 consolidated plaintiffs?

17 A. Might be an additional to the
18 three or four.

19 Q. Okay?

20 A. So it could be fifth, or fourth.

21 Q. Okay. Do you expect to receive
22 any more tissue samples from the consolidated
23 plaintiffs?

24 A. No. As far as I would understand
25 this is all what we have at this point.

1 Q. For the original tissue samples
2 that you received from Dr. Kreutzer, the 22 or 23
3 TVT or TVT-O, did you know that those samples,
4 tissue samples, were also analyzed by Dr. Jordi,
5 using analytical chemistry?

6 A. The name sounds familiar but I
7 don't know details. I don't remember, sorry. I
8 don't remember specific details, what was done in
9 that time.

10 Q. Have you ever seen any analytical
11 chemistry testing on the 22 or 23 TVT samples that
12 you received from Dr. Kreutzer?

13 A. I don't recall specific details.
14 I could have seen something, I could have not, it's
15 been quite a long time ago.

16 Q. Did you ever request that
17 analytical chemistry testing be conducted on any of
18 the mesh samples that you've analyzed?

19 A. No. I have my own methodology in
20 this; I describe what I see. Why would I ask
21 somebody else to do something else?

22 Q. So is it fair to understand that
23 for Exhibits Number 1 and 2, which is your report
24 and supplemental report, that all of the images in
25 here are TVT or TVT-O manufactured by Ethicon?

1 A. Yes. Some images were taken from
2 publications, so there was one or two panels from
3 different mesh manufacturer.

4 But the rest, when the pictures were
5 individual, they were all of TVT or TVT-O explanted
6 specimens.

7 Q. Are you able to tell me sitting
8 here today -- strike that.

9 Let's go to Exhibit 3, please. Number
10 15?

11 A. Yes.

12 Q. Number 15 asks for all materials
13 including but not limited to any protocol
14 specimens, slide raw data interim and final test
15 results, log laboratory books, notes, photographs,
16 photo micrographs and any other documents relating
17 to the pristine polypropylene control you tested by
18 exposure to formalin for up to four months
19 referenced on page 17 of your report in this case.

20 Is there any information on the thumb
21 drive from Exhibit 4 for that?

22 A. The entire protocol is really
23 simple. It was included in the paper, so it is on
24 the thumb drive; the paper is on the thumb drive.
25 I didn't have anything in addition to that.

1 Q. Is there any lab notebook?

2 A. No, I mean --

3 Q. Are there any photographs?

4 A. All photographs I had, I included
5 there.

6 Q. So whatever you have related to
7 the formalin exposed polypropylene control is on
8 the thumb drive?

9 A. In the report. The pictures are
10 on the report. The paper with description of the
11 experiment is on the thumb drive.

12 Q. What kind of polypropylene was
13 tested with formalin?

14 A. What do you mean, what kind? I
15 tested meshes of different manufacturers including
16 Ethicon TVT.

17 Q. So you did use an Ethicon Prolene
18 mesh in the formalin control test?

19 A. It was TVT.

20 Q. Okay.

21 A. It was a piece of TVT, a few
22 pieces of TVT put in formalin.

23 Q. When you say you put it in
24 formalin, did you do anything other than just put
25 it in a jar?

1 A. They were kept in formalin, in a
2 jar, and then they were put in the cassette for
3 tissue processing and then they went through the
4 whole process of xylene alcohol and everything else
5 and then I had slides made.

6 Q. And no analytical chemistry done
7 of that control, correct?

8 A. Why would I? I'm doing histology.

9 Q. I understand. No analytical
10 chemistry; is that correct?

11 A. That is correct.

12 Q. Thank you. Number 19.

13 A. Yes.

14 Q. "Request all materials related
15 to testing of intentionally oxidized
16 polypropylene that had not been
17 implanted or exposed to formalin."

18 Do you see that?

19 A. Yes, I do.

20 Q. Is there any information on
21 Exhibit No. 4 related to that kind of testing?

22 A. No, because the test is still in
23 progress. I mean, I kept part of mesh in different
24 solutions and I haven't taken them out yet. I
25 haven't examined them yet.

1 Q. Okay. Tell me what that
2 experiment does?

3 A. I did the same thing as I did for
4 formalin exposure. I took pieces of mesh and put
5 them in solutions of hydrogen peroxide, hydrogen
6 peroxide with catalysts, few strong acids,
7 solvents, and just they are stored in these
8 solutions.

9 Q. How many pieces of mesh are you
10 testing?

11 A. It's hard to say now. It might be
12 over 20 small pieces.

13 Q. And how are they stored right now?

14 A. In a dark room in a cabinet.

15 Q. In a vial?

16 A. What do you mean, vial?

17 Q. Are they in a container with a
18 cover on them?

19 A. Yes, of course. Some of them are
20 acids and they're in glass containers.

21 Q. What temperature are they being
22 stored?

23 A. Just room temperature.

24 Q. Do you have a protocol that you
25 wrote up for this test?

1 A. No. The only protocol I used was
2 there was a published paper, they introduced this
3 stimulated body environment -- simulated, not
4 stimulated. Simulated body environment. Hydrogen
5 peroxide was the catalyst. Catalyst is a chromium
6 salt.

7 Q. Cobalt chloride?

8 A. Probably.

9 Q. That's Dr. Guelcher's paper?

10 A. I'm not sure if it's his paper,
11 it's another paper. But anyway, I'm testing his
12 protocol. I followed exactly the description in
13 the paper and kept it in the solution for almost a
14 year by now, but it's still too early to take it
15 out.

16 Q. Why is it still too early to take
17 it out?

18 A. Because based on my analysis of
19 the specimens explanted from the body I can barely
20 see the degradation bark after a year in the body.
21 So if I take them now it would be too early.

22 I may just waste samples, so I have to
23 wait for probably a few extra months or maybe
24 another year. Because by year two or 1 1/2 years
25 in the body, the bark becomes visible in

1 100 percent of the cases.

2 If I take them out by 12 months, I may
3 or may not see something and then it would -- I'll
4 just waste samples.

5 Q. Did you prepare the solution in
6 which these samples are stored?

7 A. Yes, I did.

8 Q. And what is the recipe for the
9 solution that you used?

10 A. It's written in the original paper
11 I used for the --

12 Q. Can you tell me what the original
13 paper is?

14 A. I'd have to check now.

15 Q. And how many samples are stored?

16 A. As I said, probably over 20.

17 Q. And how many different kinds of
18 mesh are being tested?

19 A. There is one from one
20 manufacturer, and then -- four types of mesh.

21 Q. How many Ethicon meshes are being
22 tested?

23 A. At least one.

24 Q. What kind?

25 A. It's written on the jars. I may

1 have to check later.

2 Q. Doctor, do you have an inventory
3 of what's in each vial written down?

4 A. It's written on the jar.

5 Q. Is it written down on a piece of
6 paper anywhere?

7 A. No.

8 MR. ORENT: Objection.

9 BY MR. THOMAS:

10 Q. Is it written in a computer
11 somewhere?

12 A. No, just on jars. Jars label when
13 the case was put and what type of mesh was put in.

14 Q. When did you start this
15 experiment?

16 A. Last September.

17 Q. So it's been a full year?

18 A. Yes.

19 Q. And did you put the mesh in this
20 solution in these 20 or so samples all at the same
21 time?

22 A. Within two weeks.

23 Q. All right. As I understand it,
24 there are at least four different mesh
25 manufacturers that are a part of this experiment?

1 A. At least four different type of
2 mesh. I would have to check with the labels what
3 is written there, what manufacturers, what mesh was
4 put in there. I don't remember. It's been a year.

5 Q. Are you working with anybody else
6 on that experiment?

7 A. No.

8 Q. This is solely your work?

9 A. Yes.

10 Q. Did you consult with anybody about
11 the kind of solution that you would use for your
12 experiment?

13 A. No. Whom I would consult? Nobody
14 did it before. The only information I extracted
15 was from that specific simulation body environment
16 simulation from the paper.

17 Q. You know Dr. Guelcher has tried to
18 insulate oxidized polypropylene, don't you?

19 MR. ORENT: Objection.

20 THE WITNESS: I know that he did an
21 experiment, and he asked me what I see. I said
22 it's too early, I'm not going to take them out yet.
23 I will keep them a little longer.

24 BY MR. THOMAS:

25 Q. Did Dr. Guelcher tell you he had

1 intentionally oxidized polypropylene by exposing it
2 to some chemical solution?

3 MR. ORENT: Objection.

4 THE WITNESS: Yes, he did.

5 BY MR. THOMAS:

6 Q. Did you ask him to have that mesh
7 so that you could determine whether this
8 intentionally oxidized polypropylene absorbed
9 stain?

10 MR. ORENT: Objection.

11 THE WITNESS: No.

12 BY MR. THOMAS:

13 Q. Why not?

14 MR. ORENT: Objection.

15 THE WITNESS: Because I'm doing my own
16 experiment and I believe I need to keep it for at
17 least a year and a half.

18 BY MR. THOMAS:

19 Q. Did you discuss with Dr. Guelcher
20 the scope of his experiment?

21 MR. ORENT: Objection. At this point,
22 Counsel, I think you're getting into -- I think you
23 need to clarify whether your questions are in the
24 context of litigation or research.

25 To the extent it's in litigation it's

1 covered by privilege and I would instruct the
2 witness not to answer under the rules. But to the
3 extent that you're discussing research, I think
4 that's fair game to discuss.

5 BY MR. THOMAS:

6 Q. Okay. From a research
7 perspective, did you have any discussions with Dr.
8 Guelcher about his experiment?

9 A. It's work in progress so it's
10 privileged to researchers, I guess, at this point.

11 Q. Are you going to assert a
12 privilege for your research?

13 A. For research information, yes.

14 Q. Okay. And you asserted a
15 litigation privilege, which I don't think is
16 appropriate -- I'm not arguing with you. You said
17 there's no research privilege. Now he's trying to
18 assert a research privilege?

19 MR. ORENT: No, what I said was in
20 terms of legal -- in terms of legal privileges that
21 I can, that I have, that I have an attorney-client --
22 excuse me, a attorney work product under the Rule
23 26.

24 Rule 26 specifically allows for expert
25 witnesses to consult with one another under the

1 2010 amendments to the federal rules.

2 So, what I was clarifying is that it is
3 my privilege to seek and to utilize for my client,
4 and that's what I was exercising with regard to
5 non-research thought processes for litigation.

6 To the extent Dr. Iakovlev has
7 proprietary interests in research that is ongoing
8 or may be ongoing, that's up to him as to whether
9 or not -- and I know that on both sides in this
10 mesh litigation have previously taken a position
11 that those sort of things are not discoverable.

12 To the extent the doctor is
13 comfortable, I'd be happy to designate this portion
14 of the transcript highly confidential and allow the
15 witness to answer.

16 THE WITNESS: I also need to add that
17 that experiment is not in my opinions. I was not
18 base my opinions on any part of that experiment.
19 And I'm not really sure why you asking me these
20 questions.

21 BY MR. THOMAS:

22 Q. Because I get to ask them.

23 MR. ORENT: If I can just have a minute
24 with the witness and explain what the highly
25 confidential designation means, that may clarify

1 this.

2 MR. THOMAS: Thank you.

3 -- RECESS AT 9:42 --

4 -- UPON RESUMING AT 9:43 --

5 MR. ORENT: We can go back on the
6 record.

7 I'll just say for the record over the
8 break I just explained to Dr. Iakovlev what the
9 highly confidential designation is and that all the
10 lawyers in this litigation have all signed on to
11 it.

12 Confidentiality agreement whereby there
13 are limited distribution on each side as to who can
14 receive highly confidential information and that
15 after discussing it I believe the witness is
16 comfortable with the designation and will proceed
17 to answer.

18 BY MR. THOMAS:

19 Q. Thank you. Have you have
20 discussed with Dr. Guelcher the results of his
21 test?

22 A. Yes, I asked him what he saw.

23 Q. And what did he tell you?

24 A. He said that there is flaking on
25 the surface early, it's not confluent but there are

1 some flakes forming.

2 I said it might be too early, because
3 he did it I think on six weeks or so, maybe more,
4 maybe up to three months.

5 I said, well, I keep my specimens for
6 at least a year and a half because I believe that
7 that's much time you need to make it visible by my
8 techniques. Maybe by SCM we can see a little bit
9 earlier, and we stopped at that.

10 Q. Do you know whether he conducted
11 any analytical chemistry testing on any of the mesh
12 he analyzed?

13 A. I think he did.

14 MR. ORENT: Objection.

15 THE WITNESS: I don't remember at this
16 point. It's not my specifically methodology, so I
17 didn't do these things.

18 BY MR. THOMAS:

19 Q. Did you have discussions with Dr.
20 Guelcher about trying to stain the polypropylene
21 that he had intentionally oxidized?

22 A. He asked me. I said it's too
23 early.

24 Q. Okay?

25 A. So I said maybe by your methods

1 you can detect it. By my methods, probably I
2 cannot. And I said I will keep my pieces for
3 longer and then we'll see what happens.

4 Q. And how did you decide -- strike
5 that. Did I understand you to say that you have
6 chosen 18 months as the time when you think it will
7 be appropriate to test for oxidation?

8 MR. ORENT: Objection to form.

9 THE WITNESS: Yes.

10 BY MR. THOMAS:

11 Q. And at 18 months is it your
12 intention to remove all of those meshes from the
13 chemical solution and determine whether it's
14 intentionally oxidized?

15 A. Part of it. Probably not all of
16 them in one shot. I will start taking some pieces
17 and examining them see what happens and if I --
18 depends on what I see, I may keep them longer.

19 Q. And what kind of tests do you
20 propose to run on them after 18 months?

21 A. Histology, what I've done -- what
22 I showed in the paper.

23 Q. The same kind of tests that you've
24 run on the meshes that are contained in your
25 reports?

1 A. Similar.

2 Q. Any differences?

3 A. Don't plan on anything different
4 at this point. I may, I mean, it's work in
5 progress research. Maybe I'll find something else,
6 I don't know.

7 Q. Are you consulting with anybody
8 else on this particular experiment?

9 A. We discussed it only with Scott
10 Guelcher.

11 Q. And is the mesh that's being
12 tested pristine new mesh?

13 A. Yes.

14 Q. Never been exposed to tissue?

15 A. That is correct.

16 Q. Never been exposed to formalin?

17 A. That is correct.

18 Q. Who is paying for this testing?

19 A. Nobody. I just took chemicals
20 from our histo lab.

21 Q. Did counsel fund this experiment?

22 A. No, there is no additional
23 funding. What funding would I need for it?
24 Chemicals are in the lab.

25 Q. Where did you get the mesh?

1 A. They came from some law firms
2 during earlier cases.

3 Q. Okay. And where did you get the
4 chemicals?

5 A. I said, they are in the lab.

6 Q. Okay. So you used materials from
7 the St. Michael's histo lab to put them, and you
8 combined those chemicals in a recipe that you're
9 now exposing this polypropylene to?

10 A. That is correct. These are
11 regular chemicals that are used in histo lab.

12 Q. And the reason why you're doing
13 this test is to determine whether, first, after
14 18 months this polypropylene will oxidize due to
15 exposure to this chemical mixture, correct?

16 A. Could you repeat the question?

17 MR. THOMAS: Can you read it back?

18 -- REPORTER'S NOTE: Question read back
19 as recorded above.

20 THE WITNESS: That's correct.

21 BY MR. THOMAS:

22 Q. And how will you determine whether
23 it's oxidized?

24 A. I would see degradation layer on
25 the surface.

1 Q. And that would be by light
2 microscopy?

3 A. Yes.

4 MR. ORENT: Objection.

5 BY MR. THOMAS:

6 Q. Any other analytical technique
7 that you propose to use?

8 A. As I said, none at this point.

9 Q. And as a part of your experiment
10 do you then intend to see whether -- if you are
11 able to oxidize polypropylene, according to your
12 visual observation by light microscopy, will you
13 then see whether the oxidized polypropylene holds
14 stain?

15 A. Yes, that's the way to see it.
16 This just becomes porous and after absorbs stain.

17 Q. And the way you will test that is
18 the same way you've processed the slides in Exhibit
19 No. 1 and 2 -- you'll put them through the sample
20 preparation histology analysis that you've done in
21 all your other cases?

22 A. Can be tried without putting them
23 through histology; you can immerse exposed mesh
24 into the dye solution.

25 Q. Just drop it in the jar?

1 A. Pretty much. If it stains, then
2 you can see staining on the surface. That means
3 there is a layer of porous polypropylene on the
4 surface.

5 It's like, this is not stain, this is
6 anodized aluminum. So there's porous layer on
7 aluminum. If you drop unprepared aluminum in the
8 jar with black ink it will not absorb anything
9 because it's sealed.

10 If you drop it with anodized layer it
11 will become black because it will absorb it. It's
12 the same technique; it's pretty basic.

13 Q. I understand. Thank you.

14 Are you aware of a method where you can
15 take a piece of pristine mesh that's been exposed
16 as you've described, and prepare a histological
17 slide of that exposed material without embedding it
18 in some other medium?

19 A. Let me ask you if I got your
20 question right.

21 Am I aware of a histological technique
22 which will allow me to cut through the mesh without
23 embedding it into anything?

24 Q. Correct.

25 A. No. It has to be embedded into

1 some form of medium to hold it for the knife to cut
2 through.

3 Q. Have you devised or thought of a
4 method to do that?

5 A. No. Why would I?

6 Q. If you're going to do a histology
7 slide of this mesh that's been exposed to chemicals
8 after a year and a half, you're going to have to
9 put it in some medium before the microtome can cut
10 it, correct?

11 A. Paraffin.

12 Q. So you're going to put the mesh by
13 itself in paraffin and cut it from there?

14 A. Yes.

15 Q. Okay.

16 A. That's how it's done.

17 Q. That's fine. Doctor, on page 82
18 of your report?

19 A. Yes.

20 Q. Are you on page 82? That's where
21 I want you to be.

22 A. Oh, yes, okay.

23 Q. I'm sorry, 83. I apologize, I was
24 wrong.

25 Page 83 of your report has two images,

1 A and B, identified as Figure Set 16 A, is
2 identified as "cracking on the surface of TVT mesh
3 fibers immediately after removal from the body".

4 Where did you get this?

5 A. This was a St. Michael's patient.
6 So when it was excised I immediately placed it
7 under the microscope.

8 Q. How did you know it was being
9 excised?

10 A. What do you mean how do I know?
11 We receive specimens.

12 Q. Just so I understand -- strike
13 that.

14 Typically after a surgical procedure
15 when mesh is excised the surgeon immediately places
16 it in formalin, correct?

17 A. Not always.

18 Q. Okay.

19 A. We receive it fresh, so in this
20 case it was fresh.

21 Q. And did you discuss with the
22 surgeon any of the circumstances of removal?

23 A. This was a St. Michael's specimen,
24 so I did ask, but I'm not sure if I can go there
25 because of the confidentiality issues. It was not

1 a medical-legal case.

2 Q. Who was the doctor that you
3 discussed it with?

4 A. I don't know if I can disclose it.

5 Q. I'm going to ask you to and if you
6 tell me no, you tell me no?

7 A. Again, I'm not sure if I can
8 disclose that because it is confidential
9 information.

10 Q. Are you telling me you're not
11 going to? That's fine. Tell me you're not going
12 to and I'll move on.

13 A. No, I will not. I will not
14 because I don't want to compromise confidentiality.

15 Q. Okay. Can you tell me the nature
16 of the conversation you had with this doctor?

17 A. Oh, I asked her later on what was
18 -- because then I would ask how long it's been in
19 the body, some information was on the records and
20 just basic information.

21 Q. Did you get medical records for
22 this mesh?

23 A. It was in medical -- in the
24 medical records of St. Michael's Hospital.

25 Q. Did you produce on the thumb

1 drive, Exhibit No. 4, the medical records for the
2 patient that's on page 83?

3 MR. ORENT: Objection.

4 THE WITNESS: No, it's confidential
5 information, St. Michael's Hospital information.
6 And the picture is not coming from a case itself;
7 picture is coming from a publication.

8 BY MR. THOMAS:

9 Q. Well, it's your publication; is
10 that fair?

11 A. Yes.

12 MR. ORENT: Objection.

13 BY MR. THOMAS:

14 Q. Okay?

15 A. But it's not coming from a set of
16 TVT or TVT-O cases which are received within the
17 litigation process. It's coming from a publication
18 and for that publication I had REB approval and
19 there are strict rules what can be disclosed, what
20 cannot be disclosed.

21 Q. How long from the removal of this
22 mesh until the time you looked under the
23 microscope?

24 A. I would say an hour, maybe
25 40 minutes, maybe less.

1 Q. How did you manage to get it so
2 quickly?

3 A. We have a lab in the OR. OR is
4 practically -- I mean, our receiving area for
5 specimens is in OR, it's like there.

6 Q. Did you tell the doctor if she
7 ever got a TVT specimen that you'd like to have it
8 before it was put in formalin?

9 A. No, but I told, I told several
10 physicians and several -- everybody knows that I'm
11 working on meshes, so people know that I'm
12 interested in meshes.

13 Q. My question was, did you tell a
14 doctor to give one to you before it was exposed to
15 formalin?

16 MR. ORENT: Objection. Can I just ask
17 for clarification. Your prior question was --
18 included the word TVT. Prior testimony on this was
19 that this was not a TVT, I believe. Oh, this is a
20 TVT, I apologize.

21 THE WITNESS: In the earlier, very
22 early when we started working on these meshes, the
23 question was how do I process them for scanning of
24 -- transmission of electron microscopy, and I
25 needed fresh samples.

1 Not only specifically for this case, I
2 asked if you can sometimes help me with what you're
3 excising, or submit it in saline, so it's not
4 exposed to formalin because I needed samples to be
5 put in a glutaraldehyde. This came in saline.

6 BY MR. THOMAS:

7 Q. Was this put in glutaraldehyde
8 before you made this image?

9 A. No, it was put in saline. I
10 received it in saline, I examined it, took pictures
11 and put it in formalin.

12 Q. Other than putting it in saline,
13 was any effort made to clean the mesh prior to the
14 time that you took these images?

15 A. No, just washed them in saline,
16 that's it.

17 Q. Was it washed in saline or just
18 soaked in saline?

19 A. What's the difference?

20 Q. Well, there was no effort to wash
21 it, it was merely stored in saline before you took
22 your images; is that fair?

23 A. You immerse something in fluid;
24 it's being washed.

25 Q. Okay. Go to page 5 of your

1 report, please.

2 A. Yes.

3 Q. Down at the bottom of the page,
4 the sentence, it reads:

5 "Immediately after placement in
6 the body, foreign objects become
7 coated with human proteins before
8 appearance of the inflammatory
9 cells."

10 Do you see that?

11 A. Yes.

12 Q. What does that mean?

13 A. It means that anything you put in
14 the body will get coated by serum proteins.

15 Q. How many different kinds of
16 proteins are there in the body?

17 A. Very large number, thousands,
18 maybe millions.

19 Q. Is there a special kind of protein
20 that surrounds the foreign body?

21 A. It's non-specific. The area will
22 be filled with blood immediately, so main proteins
23 are in the serum, so it will be albumin, some
24 immunoglobins, then the blood clotting cascade sets
25 in.

1 So there will be more of a fibrinogen
2 and fibrin, all of those proteins which are
3 involved in blood clotting. It depends what
4 timeframe we're talking about, immediate coating,
5 or minutes or hours or days after.

6 Q. Do you know what protein
7 adsorption is, A-D-S-O-R-P-T-I-O-N?

8 A. You mean adherence of the protein
9 to the surface?

10 Q. Are you familiar with that?

11 A. I mean, that's the term as I
12 understand it.

13 Q. Do you know chemically how that
14 works?

15 A. For all proteins?

16 Q. For protein adsorption to foreign
17 bodies; do you know how it works?

18 A. Not the specific chemical details.

19 Q. Do you know the extent to which
20 the proteins form a bond with the foreign body?

21 A. Not the specific details.

22 Q. Do you specifically with
23 polypropylene -- or strike that. Specifically with
24 Prolene, do you have any information about the
25 extent to which human proteins form a bond with the

1 Prolene polypropylene?

2 MR. ORENT: Objection.

3 THE WITNESS: No.

4 BY MR. THOMAS:

5 Q. Do you have any information about
6 the extent to which saline is adequate to remove
7 any proteins that are adsorbed on to the Prolene
8 mesh?

9 A. No, I think it's irrelevant
10 because that mesh which was examined didn't have
11 time to dry and couldn't dry because it was in
12 saline.

13 So if it cracks it means that it had
14 time to crack. In this case it couldn't dry.

15 Q. There's no analytical chemistry
16 done on this, correct?

17 A. No.

18 Q. There are none; am I correct?

19 A. You are correct.

20 Q. Thank you. So, you're basing your
21 opinion on the cracking, which you claim to be the
22 Prolene, based on your visual observation?

23 A. That is correct.

24 Q. Let's go back to page 82, please
25 which is your statistical analysis of TVT meshes

1 analyzed as groups?

2 A. Which page number?

3 Q. I'm on 82.

4 A. Okay.

5 Q. 82 is called, "Figure Set 15, TVT
6 Meshes Analyzed as a Group".

7 And you're doing a statistical analysis
8 here of the TVT meshes; is that correct?

9 A. That's correct.

10 Q. Are the TVT meshes described on
11 page 82 the meshes that you got from Dr. Kreutzer?

12 A. Some of them.

13 Q. How many of them?

14 A. I don't remember now. Probably
15 about 20 or 19.

16 Q. And how many are in this group?

17 A. 23.

18 Q. So probably 19 or 20 out of 23
19 were meshes you got from Dr. Kreutzer?

20 A. Probably, but I'm not sure. I
21 don't remember now.

22 Q. Are you a trained statistician?

23 A. No, but I had my statistics when I
24 did my research training.

25 Q. Okay. Who chose the statistical

1 method that's employed here?

2 A. I did.

3 Q. And why?

4 A. What do you mean why?

5 Q. Why was this method the method you
6 chose?

7 A. Because it's the method to check
8 what I was intending to check.

9 Q. And tell me why that is an
10 appropriate method for what you have done?

11 A. What do you mean?

12 Q. Why is this Pearson coefficient?

13 A. Pearson coefficient? It's a
14 standard correlation coefficient method.

15 Q. Are you aware of other statistical
16 methods to test your results?

17 A. What do you mean? For
18 correlation?

19 Q. Yes.

20 A. Could be Spearman.

21 Q. Spearman?

22 A. Yes.

23 Q. Any others, R-squared?

24 A. For correlation?

25 Q. Yes.

1 A. There might be others, but the
2 main are Pearson and Spearman; there is not much
3 difference between them.

4 Q. Is the raw data you used to do
5 your statistical correlation on Exhibit 4?

6 A. Yes, it is.

7 Q. And how is it marked, so if I
8 wanted to find it, I could see it?

9 A. It's in a separate file it's
10 called 23 TVT-O and something else for the chart.

11 Q. So if I wanted to have a
12 statistician run a different model, all of the data
13 he would need to do it is on Exhibit 4?

14 A. Yes. It's there.

15 Q. Okay. Doctor, since you were last
16 deposed, you've had a couple of studies published
17 in journals?

18 A. Probably more than a couple, yes,
19 I did.

20 Q. And your deposition notice
21 requested communications with the journals about
22 publications that you produced. Are those on
23 Exhibit 4?

24 MR. ORENT: Objection.

25 THE WITNESS: I believe it's

1 confidential to me as a researcher, privileged.

2 They've been published, they've been accepted, they
3 are publicly available.

4 BY MR. THOMAS:

5 Q. Is the answer to my question no,
6 you didn't produce any of those communications?

7 A. No, I didn't.

8 Q. Do you have such communications?

9 A. Acceptance letters, that's about
10 it.

11 Q. Do you have any comments or
12 criticisms from any peer reviewers?

13 MR. ORENT: Objection.

14 THE WITNESS: There were some.

15 BY MR. THOMAS:

16 Q. Do you still have those?

17 A. Yes, I do.

18 Q. Were any of these articles
19 rejected by any journals?

20 A. Sometimes I submit to one journal
21 they say it's out of scope it's probably best
22 suited for another journal so it bounces back.

23 I don't remember specific rejection,
24 saying that the data isn't reliable. The only way
25 -- the only time when the paper was not accepted it

1 was quick answer, right away, that's not in our
2 scope.

3 Q. So how many journals did not
4 accept your publication?

5 MR. ORENT: Objection.

6 THE WITNESS: I don't remember now.

7 BY MR. THOMAS:

8 Q. Okay. Do you have that
9 information?

10 A. Probably somewhere in the replies
11 I can find it.

12 Q. Okay. Did you ever disclose to
13 the journals to which you submitted these
14 publications that some of the work contained in the
15 journal publication had been funded by plaintiff's
16 counsel?

17 MR. ORENT: Objection.

18 THE WITNESS: Nothing was funded by
19 plaintiff's counsel. They were litigation cases
20 but I didn't get any additional funding to conduct
21 the study.

22 BY MR. THOMAS:

23 Q. Certainly the slides from Dr.
24 Kreutzer were provided to you by plaintiff's
25 counsel?

1 MR. ORENT: Objection, argumentative.

2 THE WITNESS: I didn't use them.

3 BY MR. THOMAS:

4 Q. In your study? Isn't that what --

5 A. I meant I didn't use the stains he
6 used. I re-stained on stain slides. Maybe even
7 cut the blocks.

8 Q. So is it your testimony that all
9 of the information that you submitted to the
10 journals was unrelated to your medical-legal work?

11 A. No. It's not unrelated because
12 some samples came for medical-legal purposes.

13 Q. And for which you were paid to
14 analyze by plaintiff's counsel, correct?

15 A. To provide reports.

16 Q. And what percentage of the cases
17 that you report in the study were cases for which
18 you were compensated by plaintiff's counsel?

19 MR. ORENT: Objection.

20 THE WITNESS: The study was not
21 compensated by anyone. I did it on my own time,
22 during my own time, and I don't know why you're
23 saying that.

24 The percentage of cases which came
25 through medical-legal litigation process is

1 indicated in the paper.

2 BY MR. THOMAS:

3 Q. Okay. We'll get to that in a
4 minute.

5 In the last year you've traveled and
6 made presentations around the world on the research
7 that you've done?

8 A. Yes, I did.

9 Q. Who has funded that work?

10 A. Pretty much I did.

11 Q. Did anybody subsidize your trips?

12 A. No, I mean, we have a specific
13 portion of our salary from St. Michael's Hospital
14 which is dedicated for presentations. But it's
15 within my salary, it's more or less a way of
16 getting it through a different tax bracket because
17 it's money spent for -- it's within my contract.

18 Q. Did you receive any funds from
19 plaintiff's counsel for your presentations in the
20 last year?

21 A. Never.

22 Q. The articles that you had worked
23 on --

24 A. The full answer would be I paid
25 for all the trips and I never received any money

1 for making presentations or publishing the papers.

2 Q. Okay. Let's go back to page 83.

3 83 again is the mesh fiber that you looked at under
4 light microscopy 40 minutes to an hour after it was
5 removed and before it was stored in formalin,
6 correct?

7 A. That is correct.

8 Q. Where is that fiber today?

9 A. It's embedded in formalin. The
10 specimen went into formalin -- sorry. The specimen
11 went to formalin and now it's embedded in paraffin.

12 Q. Why is it in paraffin?

13 A. To take histological section.

14 Q. Have you taken histological
15 sections of it yet? Have you taken histological
16 sections of this mesh fiber yet?

17 A. Yes, I did.

18 Q. Are those reported anywhere?

19 A. What do you mean? This was St.
20 Michael's Hospital patient. I described it, and I
21 reported whatever I saw in the microscope.

22 Q. Okay.

23 A. It's not within the litigation
24 process. It's a patient outside of litigation and
25 the only way this picture made it into this report

1 because it was in a publication.

2 Q. Did you obtain permission from the
3 patient to do that?

4 A. For using the -- we have a
5 standard protocol for research. We use material
6 for research purpose and I had REB approval.

7 Q. Did you obtain permission from the
8 patient to use this image?

9 A. As I said, each person who enters
10 the hospital, academic hospital, St. Michael's
11 Hospital, signs agreements or release form and it's
12 covered by blanket research regulations.

13 Q. Does the patient know that her
14 mesh fiber was featured in a publication?

15 A. No, I didn't tell her specifically
16 to the patient.

17 Q. Okay. So the entirety of the
18 excised mesh was then placed in paraffin?

19 A. I believe so.

20 Q. Is there any remaining of the mesh
21 explant that was not put in paraffin?

22 A. I don't think so. It depends. If
23 it's a large piece, which I don't suspect it is,
24 there are some remnants which are stored in
25 formalin. In this case, probably everything went

1 to paraffin.

2 Q. So there still exists some mesh
3 material in paraffin that could be available for
4 analysis; fair?

5 MR. ORENT: Objection.

6 THE WITNESS: For histology?

7 BY MR. THOMAS:

8 Q. Yes.

9 A. Yes.

10 Q. And have you prepared histological
11 slides of the mesh fibers that are contained on
12 page 83 of your report?

13 A. Yes.

14 MR. ORENT: Objection.

15 BY MR. THOMAS:

16 Q. As I understand it, they are not
17 part of your report in this case, true?

18 A. No. As I said, this patient has
19 nothing to do with this report. The only mechanism
20 that this paper appeared in this report because it
21 was in peer-reviewed publication, that's it. Why
22 are we talking about this patient? I don't
23 understand.

24 Q. And if I wanted you to produce the
25 paraffin with the remaining mesh and the slides

1 that you have for this mesh, which is depicted on
2 83, would you do that for me?

3 MR. ORENT: Objection. I think you
4 need to deal with the hospital and privacy laws of
5 Canada. I don't think Dr. Iakovlev owns that
6 property, nor --

7 MR. THOMAS: If he's not going to do
8 it, that's all I want to know.

9 THE WITNESS: No, I will not do that.
10 As I said, the paper is published. It's public,
11 that is why it made it into this report.
12 Everything which belong to St. Michael's and
13 individual patients outside of litigation has
14 nothing to do with this report.

15 BY MR. THOMAS:

16 Q. Did you wait until it was
17 published before you used it in the report?

18 A. Yes, I did. I mean, it was
19 published by the time I produced the report.

20 Q. Okay. Did you use it in any other
21 report prior to the time that it was published in
22 the journal?

23 A. I don't think so.

24 Q. That would have been
25 inappropriate?

1 A. Before it was published, or
2 accepted -- it depends. It's my research project
3 and I'm covered by REB.

4 So if it's within my research and
5 knowledge it would be appropriate because I conduct
6 research, that's information I extract during my
7 research.

8 Q. So if you used it in a report
9 against Ethicon prior to the time that it was
10 published in the journal, that's okay, because it's
11 a product of your independent research under the
12 REB; is that correct?

13 A. Yes.

14 (Reporter sought clarification.)

15 A. Research Ethics Board.

16 Q. Is the Research Ethics Board the
17 Canadian equivalent of the American Institutional
18 Review Board; do you know?

19 A. No, no.

20 Q. What's the difference?

21 A. Ethics board is individual for
22 specific institutions. Each institution has their
23 specific research ethics board.

24 Q. What does the REB do?

25 A. They review your application.

1 They see if there can be any harm to the patients,
2 then they approve your methodology.

3 Q. And do you have a written document
4 from the REB that approves your mesh research work?

5 A. Yes.

6 Q. Is there more than one that you
7 have from there?

8 A. There was renewal.

9 Q. Did you submit an application to
10 them for this REB approval?

11 A. Yes, of course.

12 Q. And you have that application
13 still?

14 A. Yes, I should.

15 Q. What other documents did you have
16 in your possession related to your request for, or
17 their approval of your research in meshes?

18 A. Nothing. Just application and
19 their approval letter.

20 Q. Did you have to appear before the
21 REB to represent on your research?

22 A. No, it's a simple, it is a very
23 simple project. I don't do anything to the
24 patient. I don't do anything specific.

25 I do exactly what I do every day, so it

1 was straightforward. It couldn't be any hard, just
2 examining histologically.

3 Q. Let's take a break.

4 -- RECESS AT 10:19 --

5 -- UPON RESUMING AT 10:26 --

6 BY MR. THOMAS:

7 Q. Doctor, going back to the images
8 on page 83 of your report, did you write a
9 pathology report of your findings for your review
10 of the histology?

11 A. Probably I did. Maybe I haven't
12 completed it yet. With the meshes, I'm slow, so I
13 could have completed the report, could have not. I
14 don't remember now.

15 Q. What's your practice for doing a
16 pathology report for a patient in the hospital who
17 is not involved in medical-legal? Do you turn that
18 around pretty quickly?

19 A. What do you mean is not involved
20 in medical-legal?

21 Q. I thought you told me this was not
22 a medical-legal case, this mesh that's on page 83
23 of your report?

24 A. That's correct.

25 Q. So, have you done a pathology

1 report for this patient based on your review of the
2 histology of her mesh?

3 A. Doesn't matter medical-legal or
4 not medical-legal, when I collect mesh specimens
5 because my work is done so slow, I think and it
6 takes me time. It has nothing to do with
7 medical-legal or not. The difference is mesh
8 versus no mesh.

9 Q. Have you prepared any -- have you
10 dictated anything related to the histology from the
11 mesh ex-plant that's depicted on page 83 of your
12 report?

13 MR. ORENT: Objection.

14 THE WITNESS: I don't remember.

15 BY MR. THOMAS:

16 Q. Have you written anything about
17 your review of the histology from the explanted
18 mesh that's based on page 83 of your report?

19 MR. ORENT: Objection.

20 THE WITNESS: As I said, I don't
21 remember. I've written something, because there
22 was a gross description at least there at the
23 beginning of the report. Maybe it's signed out, I
24 don't remember now. I use exactly the same format
25 for all mesh specimens litigation, non litigation.

1 BY MR. THOMAS:

2 Q. I understand that.

3 A. And because there are so many
4 items I'm checking it takes me time and I don't
5 want to do it in a rush.

6 With cancer cases it is a different
7 story. I rush, I try to make sure diagnostic
8 process is not involved. In this case the mesh is
9 out already so there is no pressure.

10 Q. So to your knowledge, you don't
11 know whether the doctor or the patient had the
12 benefit of your pathological review of the
13 histology, correct?

14 A. I think I described it for the
15 physician.

16 Q. How did you describe it to her?
17 In writing or voicemail or person to person?

18 A. I don't remember now. I'm not
19 sure where we're going with this, this is
20 confidential, and I'm not comfortable getting into
21 confidential information of a St. Michael's
22 Hospital patient.

23 The paper has been published and the
24 picture made it in the report after the publication
25 was peer reviewed and accepted.

1 Now we're getting into completely
2 different area and I said I'm not getting
3 comfortable in getting into confidential
4 information of a St. Michael's patient.

5 Q. I'm trying to figure out whether
6 anything in writing exists to your knowledge that
7 describes the findings you made based upon
8 histological review of this explanted mesh.

9 MR. ORENT: I think he's answered those
10 questions. I think he's gone far beyond his
11 comfort level. Let's move on.

12 MR. THOMAS: Are you instructing him
13 not to answer?

14 MR. ORENT: I'm not. However, if he
15 believes that he's confined by Canada's
16 confidentiality laws it's up to him in terms of his
17 knowledge, and what he can share as a doctor over a
18 patient who is not at issue in this lawsuit and not
19 put their medicals at issue.

20 THE WITNESS: As I said, I'm not
21 comfortable getting into further details. I think
22 it's inappropriate. This picture appeared in the
23 report because it was published.

24 BY MR. THOMAS:

25 Q. Doctor, on page 8 through 11 of

1 your report, you have a section titled
2 "Polypropylene Degradation and Review of Ethicon's
3 Internal Documents"?

4 A. That is correct.

5 Q. How did you determine what
6 documents to review from Ethicon?

7 A. I asked to send me anything which
8 was available pertinent to polypropylene
9 degradation, specifically if Ethicon scientists
10 performed testing using similar technology and
11 methodology, histology mainly.

12 Q. Did you rely on counsel to provide
13 to you the documents that you reviewed?

14 A. Yes.

15 Q. Did you produce for us on
16 Exhibit 4 all of the documents that you reviewed?

17 A. Yes, I did.

18 Q. Were there other documents that
19 plaintiff's counsel supplied to you that you did
20 not include on Exhibit 4?

21 A. Not to the best of my knowledge.

22 Q. All right. You also refer to
23 deposition testimony of Thomas Barbolt?

24 A. Yes.

25 Q. Is Dr. Barbolt's deposition on

1 Exhibit 4?

2 A. Yes, it is.

3 Q. Do you remember how many days his
4 deposition was?

5 A. I think there were two days.

6 Q. Did you read the whole thing?

7 A. I read most of the deposition.

8 Skimmed, I mean it's really long document.

9 Q. Do you recall what his job was at
10 Ethicon?

11 A. I don't recall now.

12 Q. Do you know what his training was?

13 A. No.

14 Q. Do you know what kind of testing
15 Dr. Barbolt conducted while he was at Ethicon?

16 A. I don't remember now.

17 Q. Do you know whether he conducted
18 any animal testing of mesh?

19 A. I saw documents of animal testing,
20 many documents. If he was part of all of them or
21 some of them, I don't remember.

22 Q. Do you know whether he conducted
23 any tissue reaction studies?

24 A. I don't remember that, no.

25 Q. Do you know whether Dr. Barbolt

1 compiled and reviewed testing on Prolene
2 polypropylene from the 1960s to the present?

3 A. As I said, there were many
4 documents and it's hard for me to remember now.

5 Q. Do you know -- strike that. Is it
6 fair to understand that to the extent Dr. Barbolt
7 presented any testing in his depositions you have
8 not reviewed that testing?

9 MR. ORENT: Objection.

10 THE WITNESS: As I said, I was asking
11 counsel to provide specific information, specific
12 topics. So they provided this information and I
13 received a number of documents.

14 I specifically didn't even check
15 whoever signed this, who were the names.

16 BY MR. THOMAS:

17 Q. Did you review any of the testing
18 Dr. Barbolt reviewed in his deposition?

19 A. As I said --

20 MR. ORENT: Objection.

21 THE WITNESS: I don't remember the
22 names. The only reason I remember his name because
23 it was the only deposition I had specifically for
24 that specific subject.

25

1 BY MR. THOMAS:

2 Q. What testing do you recall
3 reviewing as a part of your review of the Ethicon
4 documents in the case?

5 A. As I said, I was focused mainly on
6 histological examination but I also skimmed through
7 the testing which was done using scanning electron
8 microscopy and just regular light microscopy.

9 Q. Did you have see any histological
10 examination of what was described as cracked
11 polypropylene sutures?

12 A. Yes.

13 Q. And what did you find in your
14 review of the histological examination?

15 A. I was really surprised. They
16 found exactly what I found 30 years before I did.
17 I did it independently; I didn't have those
18 documents before. So I thought I was Columbus, but
19 I guess I wasn't.

20 Q. And you say they found exactly
21 what you found?

22 A. Yes, exactly the same. Even
23 arrows were so much like mine.

24 Q. What was it that they found which
25 was exactly what you found?

1 A. There is a degradation bark and it
2 retains histological dyes, and it also retains the
3 granules of blue fibers. And they also used
4 polarized light.

5 I think you asked me earlier in the
6 deposition who was using polarized light before.
7 Your scientists were.

8 Q. Is it your opinion that Ethicon
9 conclusively found exactly what you found?

10 A. Yes.

11 Q. And that's based on the documents
12 that have been provided to you?

13 A. Yes.

14 Q. Did you see any histological
15 examination of the sutures that analyze to the
16 extent to which it created any risk of harm to
17 patients?

18 A. I don't think I understand your
19 question.

20 Q. What don't you understand about
21 it?

22 MR. ORENT: Objection.

23 BY MR. THOMAS:

24 Q. Let me start over again. During
25 the course of your review of Ethicon documents, did

1 you review any documents where Ethicon scientists
2 reviewed histological slides of tissue samples
3 containing mesh that was described as having
4 cracks?

5 A. Yes, I did.

6 Q. And do you recall what the tissue
7 reaction was that they described in those samples?

8 A. Yes, I do.

9 Q. And what is that?

10 A. It is the same thing which I saw,
11 fibrosis foreign body reaction formation.

12 Q. Do you know how the description
13 they found in their documents compares to what the
14 tissue reaction as described for Prolene sutures at
15 the time that it was approved by the FDA in 1969?

16 MR. ORENT: Objection.

17 THE WITNESS: The documents I reviewed
18 they were dated in '80s.

19 BY MR. THOMAS:

20 Q. I understand that.

21 A. They had exactly the same
22 description as earlier papers or papers after that.
23 So I don't think there is any difference in any of
24 the descriptions.

25 Q. Okay.

1 A. Either at time of filing of the
2 FDA application or after, it's all the same.

3 Q. And the findings that they found
4 in the '80s and the findings that they found
5 earlier, and the findings that they reported later
6 are just the same as yours are?

7 A. Pretty much.

8 Q. Okay. You say on page 9 of your
9 report at the end of the first paragraph:

10 "An important conclusion should
11 be made that if chemical and
12 physical properties have material
13 change while it is in the body, it
14 should not be used for permanent
15 applications and for anatomical
16 sites from which the devices cannot
17 be safely removed."

18 Did I read that correctly?

19 A. Yes, you did.

20 Q. Does St. Michael's use Prolene
21 sutures?

22 A. Yes, I understand they do.

23 Q. Does St. Michael's use Prolene
24 hernia mesh?

25 MR. ORENT: Objection.

1 THE WITNESS: I see it removed.

2 Probably it's used for hernia mesh as well.

3 Prolene or Marlex, I'm not sure. There are newer
4 meshes coming on the market.

5 BY MR. THOMAS:

6 Q. Does St. Michael's use Prolene
7 polypropylene mesh for the treatment of stress
8 urinary incontinence in TVT and TVT-O?

9 MR. ORENT: Objection.

10 THE WITNESS: I don't think so.

11 BY MR. THOMAS:

12 Q. Do you know?

13 A. Maybe in the past. Right now I
14 just receive them when they're removed.

15 They've been using them before. I
16 don't know if they still using it right now.

17 Q. Have you told St. Michael's to
18 stop using Prolene polypropylene sutures?

19 A. Not sutures. I talk to
20 gynecologist. I show them what my research found,
21 what I found, let them know, what's, what's my
22 opinion about this.

23 Q. Who did you talk to at St.
24 Michael's about that?

25 A. Our gynecologist.

1 Q. I'm sorry?

2 A. Our gynecologist.

3 Q. And who is that?

4 A. I don't think I can go there.

5 Again, I'm not comfortable getting into specific
6 information which is not relevant to my report.

7 Q. What did you tell that person?

8 A. I shared my research, what I
9 shared in my papers.

10 Q. Did you tell them that St.
11 Michael's should not use Prolene polypropylene?

12 A. I'm not making any guidelines.
13 I'm not a regulating body. As a researcher I can
14 share my opinion, my findings, with colleagues.
15 And that's what I do in my publications and that's
16 what I did in my personal conversations and
17 personal contacts with St. Michael's physicians.

18 Q. When did you have those
19 conversations?

20 A. Throughout. I've been involved in
21 these meshes for the last year, maybe over a year,
22 I don't remember now. First it was hernia
23 surgeons, then gynecologists.

24 Q. So you've spoken to hernia
25 surgeons at St. Michael's about the use of

1 polypropylene mesh?

2 A. That's how it came, it came
3 through hernia surgeons. The whole research
4 project came through hernia surgeons.

5 Q. Do you know whether hernia
6 surgeons at St. Michael's are still using
7 polypropylene mesh?

8 A. Probably they do. But not all of
9 them. Some of them do, some of them don't.

10 Q. Do you know whether St. Michael's
11 continues to use polypropylene mesh for the
12 treatment of stress urinary incontinence?

13 A. As I said, I know they've used it.
14 I don't know if they're still using it right now as
15 we speak.

16 Q. Did you ever tell them as a
17 scientist and pathologist that they should stop
18 using Prolene polypropylene mesh because it was
19 harming their patients?

20 MR. ORENT: Objection.

21 THE WITNESS: I described pathological
22 findings and I disclosed everything I found in the
23 specimens which were coming to me as part of St.
24 Michael's Hospital and what I found during the
25 course of my research. Yes, I did disclose all of

1 this.

2 They are independent practitioners.

3 They collect information from peer-reviewed
4 studies. They see the evidence which is published.

5 I'm one piece of the puzzle, one piece of the
6 information.

7 They make their own decision. They're
8 licensed physicians and there are regulating bodies
9 which give guidelines.

10 Again, they are free to use my
11 guidelines in my research or anything else and
12 advise their patients what is the best course and
13 what can be complications.

14 BY MR. THOMAS:

15 Q. Who was the person at St.
16 Michael's who makes the decision whether to use
17 polypropylene mesh?

18 A. Each individual physician makes
19 own decisions after discussion with the patient.
20 That's my understanding.

21 I don't think there is any guiding body
22 in specific hospital which can stop physicians from
23 using specific device.

24 Q. When you said you went to the
25 gynecologist, there's more than one gynecologist at

1 St. Michael's, isn't there?

2 A. Yes, but not all of them are
3 dealing with stress urinary incontinence. There is
4 a degree of specialization. Some of them do it,
5 sometimes some people specialize more in the field.

6 Q. There's more than one hernia
7 surgeon, isn't there?

8 A. Yes, correct.

9 Q. Is there someone over both of
10 those specialties that can determine that the
11 hospital should not use polypropylene sutures or
12 mesh?

13 A. I don't know if it can be done.

14 Q. Have you ever made an effort to do
15 that?

16 A. To stop them?

17 Q. (Nods).

18 A. As I said, I don't know if it can
19 be done.

20 Q. Have you ever made an effort to
21 stop St. Michael's Hospital from using Prolene
22 sutures or Prolene mesh other than the
23 conversations you had with a gynecologist and a
24 hernia surgeon?

25 A. No.

1 Q. Thank you.

2 What did Dr. Barbolt say about the
3 clinical significance, if any, of surface cracks on
4 polypropylene implanted in the dog study?

5 A. I don't remember now.

6 Q. What did Dr. Barbolt say about the
7 molecular weight of the Prolene sutures implanted
8 in the dog study after seven years?

9 A. I don't remember now.

10 Q. What did he say about the --
11 strike that. What did Dr. Barbolt say about the
12 physical properties of the Prolene sutures
13 implanted in the dogs after seven years?

14 MR. ORENT: Objection.

15 THE WITNESS: I don't remember now.

16 BY MR. THOMAS:

17 Q. Page 11 of your report. You talk
18 about effect on the tissue, we're talking about
19 pain -- sorry, I'm on the wrong page.

20 It's on page 12, I'm sorry.

21 A. Okay.

22 Q. Page 12, it says:

23 "It is important to note that
24 in hernia surgery, chronic pain
25 after mesh repair is a growing

1 problem. Prophylactic neurectomy is
2 offered as a method to reduce
3 incidence of pain after mesh
4 repair."

5 What is a prophylactic neurectomy?

6 A. When you cut the nerves before you
7 put the mesh in anticipating the mesh is going to
8 cause pain.

9 Q. When you say cut the nerve, what
10 kind of nerve are you going to cut in the hernia
11 surgery?

12 A. There are three main nerves
13 branches: Genitofemoral, inguinal, um, some names,
14 um...

15 Q. Any other nerves as a part of the
16 hernia surgery?

17 A. There are three branches, which
18 can be identified visually. They are thicker
19 trunks. There is a variability between people, but
20 they're called triple neurectomy because in most
21 people there will be three branches supplying
22 innervation to the area.

23 Q. So tell me what is done and why
24 it's done in hernia surgery with prophylactic
25 neuroectomy?

1 A. It depends. There's different
2 techniques. Either the branches can be cut in the
3 area, so there will be three branches identified
4 and transected, buried in muscle. The stumps will
5 be buried in muscle.

6 It could be also arthroscopic
7 techniques when they go and try and cut the nerve
8 trunks closer to the spinal cord.

9 Then I'm not sure if it will be three
10 branches, because if you go proximally it will be
11 less branches, they will all merge into larger
12 trunks. So you cannot call it triple neurectomy at
13 that level.

14 But the basic rule, we try to identify
15 supply innervation, either larger trunk or smaller
16 branches, transect them and bury the stump in the
17 muscles, so it doesn't form traumatic neuroma.

18 It's done because you want to denervate
19 the area where you anticipate the mesh is going to
20 cause pain.

21 Q. Why is it important to note the
22 prophylactic neurectomy in your report?

23 A. Because when chronic pain due to
24 mesh occurs, going back into the scarred area,
25 obstructed by the mesh, proved to be hard.

1 So historically, first there were
2 meshes put in, and then more meshes put in, and
3 then more patients started coming back as chronic
4 pain, taking the mesh out was difficult, there was
5 large defect.

6 So somebody came up with the idea,
7 let's leave the mesh in but try to denervate the
8 area, either bury the nerves with some chemicals
9 like alcohol, or put nerve blocks, which was an
10 effective strategy.

11 You anesthetize the area, so the nerve
12 doesn't work for few weeks, and then the pain would
13 be gone.

14 And then somebody came up with this
15 idea of more permanent denervation, when the area
16 is anesthetized by cutting the nerve.

17 And then first surgeons try to do
18 neurectomy or transection of the nerve after mesh
19 repair, and after some experience they figure out
20 it's really hard to do to find the nerves from the
21 old scarred area.

22 So somebody offered, okay, if we
23 anticipate the pain developing from mesh, let's cut
24 the nerve before, when the area is clean and there
25 are no scarring or mesh in the area.

1 Q. Is that an accepted surgical
2 technique to do a nerve neurectomy prior to mesh
3 implantation?

4 A. Yes, it is. It's offered, it's
5 published and there are results.

6 Q. Is that a common occurrence with
7 mesh implantation?

8 MR. ORENT: Objection. Vague.

9 THE WITNESS: Depends on the surgeons.
10 Some surgeons believe in this and they do it.
11 Depends probably on the group of surgeons' practice
12 habits.

13 BY MR. THOMAS:

14 Q. Right above that section on the
15 prophylactic neurectomy, you discuss the mesh scar
16 complex and its "interlocking and
17 compartmentalizing nature". What is the
18 interlocking and compartmentalizing nature of the
19 mesh scar complex?

20 A. So if we look at the mesh, mesh is
21 a structure, three-dimensional structure made out
22 of mesh fibers or mesh filaments.

23 So filament of fiber, circles around,
24 loops around, and then it forms in pores, and in
25 these tissues. And each pore has 360 degrees of

1 surrounding fibers, that's why it is a pore.

2 So it becomes a compartment. An area
3 which is surrounded by something or a physical
4 structure with volume inside, that is a
5 compartment. So the mesh introduces all these
6 micro compartments.

7 Q. There aren't walls around each of
8 these compartments, are there?

9 A. Yes, there are. Fibers, mesh
10 fibers, they form the walls of this compartment.

11 Q. But they don't totally encapsulate
12 -- strike that.

13 The compartment though, has an opening
14 on either side much like a screen, correct?

15 A. Yeah, more like a screen or a
16 tube. To a degree, because mesh is not completely
17 flat, it's a more of a three-dimensional. If you
18 go with microscopic level, it's three-dimensional.

19 So I would compare it with each pore as
20 a very complex irregular tube, more or less.

21 Q. My point is, instead of a
22 compartment it is a tube with openings on either
23 side?

24 A. A compartment is a tube. All
25 compartments in human body are tubes.

1 Q. That has an opening on either
2 side?

3 A. Yes, that's how they are in the
4 body. If we talk about tunnel syndromes in the
5 hand or in the chest, all these compartments form a
6 tube.

7 And the tube lets nerves and blood
8 vessels through and if compartment syndrome occurs,
9 it compromises the nerves in the vessel, in the
10 tube-like structure.

11 Q. Doctor, in your report you
12 discussed the concept of mesh stiffening?

13 A. Yes, I did.

14 Q. Please tell me how mesh stiffens?

15 A. Immediately after placement, it
16 can fold and curve. So two layers or three layers
17 of mesh is different than one layer. So this is
18 initial step, if it folds or curls or wrinkles
19 immediately after placement.

20 Then next step which will increase
21 stiffness of the structure is scar encapsulation.
22 So scar immobilizes the fibers in the structures so
23 they can not move inside the elasticity of the
24 meshes, mainly because of the bending ability of
25 the fibers and movement within the structure.

1 When it's used with scar it cannot so
2 that is lost. When it's incorporated in scar
3 tissue, the movement and bendability of fibers is
4 limited.

5 Q. Let me ask you a question here; I
6 don't mean to interrupt you. Is folding or curling
7 a necessary part of mesh stiffening?

8 A. No. It's one of the processes
9 which increases mesh stiffness if you compare it
10 with the flat product.

11 Q. So you can have, as far as you're
12 concerned, mesh stiffening if the mesh does not
13 fold or curl?

14 A. Then other mechanisms will set in.

15 Q. But the first one deals with
16 folding, curling and then the scar that you just
17 described?

18 A. Yes.

19 Q. I didn't mean to interrupt you.
20 Is there anything else you wanted to say about that
21 mechanism?

22 A. And then slowly over the years,
23 the degradation layer will start building up and we
24 know it's brittle. Like any other plastic, we see
25 over time it starts cracking. It becomes harder

1 and less flexible and it breaks.

2 Q. The degradation layer you
3 described is four to five microns?

4 A. It depends. It depends how long
5 it's been in the body.

6 Q. Is four to five microns about the
7 largest you've seen?

8 A. No, I've seen up to seven or
9 eight. Depends on the type of mesh, I guess --

10 Q. Well, Prolene polypropylene, what
11 is the largest you've seen?

12 A. It's hard to say because it's for
13 -- currently that mesh is -- 80 percent of the time
14 I don't actually know what the product is.

15 Q. 80 percent of the time you don't
16 know what the product is?

17 A. Yes.

18 Q. And the reason why I ask is, in
19 all the reports I've seen, I've never seen you give
20 an opinion that is greater than five microns to a
21 Prolene mesh?

22 A. That's just happened with any
23 litigation process, but I have over 300 meshes in
24 my office.

25 I'm just telling you the thickest bark

1 as far as I remember was up to seven, probably just
2 over seven microns thick.

3 And I think it was a hernia mesh and
4 for hernia meshes, when they've been in the body
5 for like 12 or 14 years, it's very difficult to
6 trace what type of mesh was put in.

7 Q. Your best recollection insofar as
8 you're dealing with Prolene mesh for the treatment
9 of stress urinary incontinence, the largest you've
10 seen is five microns, correct?

11 MR. ORENT: Objection.

12 THE WITNESS: Probably six, I don't
13 remember now.

14 BY MR. THOMAS:

15 Q. This bark, as you've described it,
16 by definition is cracking?

17 A. Yes.

18 Q. And when you get past the bark
19 layer the interior of the polypropylene as best as
20 you can tell is unaffected?

21 A. Yes.

22 Q. Okay.

23 A. The core of the fibers remains, at
24 least, the same by my methods.

25 Q. And by your methods, as far as you

1 can tell, past the five microns or so, the physical
2 properties of the polypropylene remain the same,
3 true?

4 MR. ORENT: Objection.

5 THE WITNESS: By my methods, yes.

6 BY MR. THOMAS:

7 Q. Have you described -- you've
8 described two ways that you believe that mesh
9 becomes stiff.

10 Are there any other ways that you
11 believe mesh becomes stiff in the body?

12 A. Three. So multi layering, scar
13 encapsulation and then degradation. No, I don't
14 know any other mechanism for stiffening.

15 Q. And the way that you're able to
16 identify multi layering is when you analyze the
17 mesh after it's been sent to you in formalin from
18 the surgeon, correct?

19 A. As I said, sometimes I receive
20 meshes fresh in saline or not just -- and I see
21 it's folded already.

22 Q. The only polypropylene meshes that
23 you've given us, other than the one that you've
24 given us limited information about, come to you in
25 formalin, correct?

1 MR. ORENT: Objection.

2 THE WITNESS: For litigation cases?

3 Meshes come in formalin, that is correct. But in
4 St. Michael's Hospital, when they receive mesh, as
5 I mentioned, everybody knows I'm the mesh guy.
6 They call me when they receive a mesh, sometimes I
7 receive them fresh.

8 BY MR. THOMAS:

9 Q. Do you have any documents, images
10 or any other information about meshes that you've
11 received fresh, without formalin, that show folding
12 or curling?

13 MR. ORENT: Objection to form.

14 THE WITNESS: I describe them when I
15 receive them. But again, we're going to the St.
16 Michael's Hospital patients and I don't want to go
17 there. I'm not comfortable discussing this
18 confidential information.

19 BY MR. THOMAS:

20 Q. Okay.

21 A. Probably took some pictures at
22 some time.

23 Q. You have not produced those
24 pictures to us?

25 A. They're not in the report.

1 They're confidential information and I took them
2 because in the course of my work as a pathologist
3 at St. Michael's.

4 Q. Do you have any information about
5 the incidents of folding or curling in mesh
6 implanted -- in Prolene mesh implanted for the
7 treatment of stress urinary incontinence?

8 A. For stress urinary incontinence,
9 the degree of curling is visible in most of the
10 cases.

11 Q. More than half?

12 A. I would say more than half.
13 Again, it depends. Sometimes one piece is curled,
14 the other one is completely flat.

15 Q. And again, these are cases where
16 you've received the mesh in formalin?

17 A. Yes. But I mean we're talking
18 about curling, not curling on the whole specimen.
19 We're talking about curling as it sits in scar
20 tissue.

21 So whatever curling I'm assessing as is
22 significant is on that, that which can -- which is
23 immobilized by scar tissue.

24 So I'm not talking about curling which
25 occurs secondary to fixation. I'm talking about

1 curling which occurred in the body. I'm able to
2 distinguish between one and the other.

3 Q. How?

4 A. I just said. If it's curled and
5 it's completely surrounded, integrated in scar
6 tissue in curled shape, it occurred in the body.

7 If the entire specimen is curled
8 together with scar, that could have been an
9 artifact. So I immediately disregard the shape or
10 the formation which occurred as an artifact.

11 Q. Let's go to page 19 of your
12 report, please.

13 A. Um-hum.

14 Q. I'm going to refer you back to
15 page 14, because I think that that's the commentary
16 that you have on that. So you've got 19, which is
17 the images, and page 14 is the text.

18 A. Yes.

19 Q. Okay. As you look at page 19,
20 Figure Set 1a is described as:

21 "A foreign body inflammatory
22 reaction H&E, 40X images
23 consolidated cases."

24 What are you showing here?

25 A. Foreign body type inflammatory

1 reaction.

2 Q. Is there anything unusual about
3 this foreign body reaction?

4 A. What do you mean unusual?

5 Q. Is there anything remarkable about
6 it? There's a foreign body reaction anytime you
7 have an implant, correct?

8 A. Then usually it's not normal
9 tissue. Normally there shouldn't be any
10 inflammation in the tissue.

11 Q. Okay. And so would there be
12 inflammation regardless of what kind of foreign
13 body is placed in there?

14 A. Yes, because having a foreign body
15 in the body is not normal thing.

16 Q. And so is it fair to say that
17 Figure Set 1a describes a typical foreign body
18 reaction to implanted materials?

19 MR. ORENT: Objection.

20 THE WITNESS: I wouldn't say typical,
21 although you can use that word. I would say
22 non-specific reaction to a foreign body. The body
23 is trying to destroy the foreign body because it's
24 a noxious stimulus, a noxious or damaging object.

25

1 BY MR. THOMAS:

2 Q. The images on the left show that
3 the polypropylene was removed as part of the
4 microtoming process; correct?

5 A. Could you repeat that question.

6 Q. I'm looking at the figures on the
7 left, which show the white images, compared to the
8 right, which show the yellow.

9 And on the left it shows that the
10 polypropylene that used to be where the white is
11 has been removed as a part of the microtoming
12 process; correct?

13 A. No, actually, there might be all
14 of them present there. They're just clear;
15 polypropylene is clear. If it is not degraded,
16 it's completely clear.

17 If the fibers were blue fibers, they
18 would be visible. If it's clear fiber they would
19 not.

20 So technically, looking at these
21 images, we cannot say which hole is the actual MTM,
22 and which sort of appear in holes, still contain
23 polypropylene. You would need polarized light to
24 see that.

25 Q. So what can you tell me about the

1 part of the mesh that we're seeing in Figure 1a?

2 A. Specifically, I don't -- do you
3 want me to discuss a specific feature?

4 Q. For example, you don't have a
5 clean cut where you're looking at a perfectly round
6 portion of the mesh, correct?

7 MR. ORENT: Objection to form, to the
8 use of the term "clean cut".

9 THE WITNESS: Some of them are closer
10 to perpendicular orientation. Some of them are
11 angled.

12 BY MR. THOMAS:

13 Q. Okay. For example, when you have
14 a microtoming process and you pull the knife across
15 the histological slide, sometimes you will create
16 an artifact by pulling the tissue away from the
17 polypropylene, correct?

18 A. Yes, because polypropylene is
19 harder than tissue, you can damage tissue during
20 cutting.

21 Q. And you can't tell if you look at
22 set 1a whether the polypropylene is there or not;
23 true?

24 A. Yes, that's true.

25 Q. You can't tell by looking at the

1 figures in set 1a whether those are the actual size
2 of the hole that was occupied by the polypropylene,
3 and whether that is an artifact from microtoming?

4 A. That I can tell you because
5 artifact from microtoming looks completely
6 different. These are holes from fibers.

7 Q. Completely?

8 A. For these specific holes?

9 Q. How can you tell the difference?

10 A. Well, you have to work as I
11 pathologist for so many years and then you can
12 tell.

13 But generally, how we go for that
14 specific feature, it would be shape, rounded shape,
15 oblique, assuming, if we look at this image here --
16 if you want me to point, circle.

17 Q. I'll give you a red pen -- let's
18 give you a blue pen. That will show up better.

19 A. Assuming if we see this tissue,
20 this specific, this is displaced. So when the
21 fiber was not cut, it probably had different
22 position, different orientation. Because it's
23 misplaced, it doesn't completely circle here.

24 Q. Is that an artifact from the
25 microtoming process?

1 A. To a degree.

2 Q. Okay.

3 A. Now, see this empty space here?

4 Q. Mark that A. Mark the first one
5 A, and the next one B, so the record is clear what
6 you've just done.

7 A. (Witness complies).

8 Q. This one will be A. That's the
9 one you've discussed first. The other one you're
10 discussing now is B.

11 A. So this circle labelled A moved
12 during microtomy. It was within the fibers and now
13 it moved, it changed position slightly.

14 The area B appears empty, but it was
15 occupied in vivo, and this is an artifact. Another
16 artifact here is artifact C, which is tissue
17 retraction. Now, if we --

18 Q. And those are all caused by the
19 microtoming process?

20 A. No. Different combination of
21 factors which cause all of this.

22 Now, if we look at the entire opening
23 marked as D, is perfect round shape, no tissue is
24 displaced. So this would be as close as it gets to
25 the area which is occupied by a cross-section of

1 the mesh fiber.

2 Q. Okay. Let's go now to the next
3 page, page 20. Anything else remarkable about that
4 page, page 19?

5 A. It depends what you want me to
6 describe.

7 Q. Well, I've seen you testify
8 before. And you put these images up on the screen
9 and you tell the jury what you think is remarkable
10 about them?

11 A. Do you want me to go through this
12 description?

13 Q. Do you have anything other than a
14 foreign body reaction, as depicted in the tissue,
15 is there anything other than that that's remarkable
16 about the images on 19?

17 A. This picture is actually good in
18 terms of it shows this layering.

19 So the fibers are surrounded by this
20 dense foreign body type inflammation, and then the
21 inflammation is actually encapsulated by dense scar
22 on the outside, so this very dense pink area is a
23 scar. So it goes on the outside of the
24 inflammation.

25 And then beyond the scar plate, here is

1 the transition into normal lighter tissue not as
2 densely scarred or densely collagenized.

3 So this picture is a good example of
4 showing this multilayering, sort of onion skin
5 around the mesh fibers.

6 Q. Anything else?

7 A. No.

8 Q. Let's go to page 20 now.

9 A. Now, I have the mark coming
10 through. Should I use a pen?

11 Q. We'll do that next time, we'll
12 take that away.

13 Now on page 20, again, this is an image
14 from the consolidated cases?

15 A. That's correct.

16 Q. And as you look in the top on 1b,
17 you see blue. And that is polypropylene mesh.

18 A. Yeah, that's a cross-section of a
19 blue polypropylene fiber.

20 Q. And it looks like it's been folded
21 as a part of the microtoming process; is that fair?

22 A. It's not microtoming process; it
23 folds, curls. Polypropylene just tends to curl.

24 Q. But this is a four-micron thick
25 slice of polypropylene, correct?

1 A. Then it curls up like this. Some
2 of them just stay flat. Some of them curl up.

3 Q. But this is an artifact of the
4 sample preparation process?

5 A. Curling? Yes.

6 Q. So the curling of the blue
7 polypropylene in set 1b on page 20 is an artifact
8 of the sample preparation process?

9 A. That's correct.

10 Q. All right?

11 A. The exact shape of that slice is
12 better to be estimated by the tissue which
13 surrounds it because tissue didn't curl, didn't
14 move much. There is more movement of the
15 polypropylene slices.

16 Q. What does that mean? I don't
17 understand.

18 A. Well, see, when the tissue is cut
19 it doesn't curl, it doesn't wrinkle most of the
20 time because of the technology of the slides and
21 knives. Everything was designed to keep it flat.

22 So over the years, over the hundred
23 years we learned how to keep it flat. With
24 polypropylene, because it is a different material,
25 doesn't stick. The histological slides don't hold

1 it as well so it's not firmly attached.

2 So, when it's cut initially, it may
3 stay flat. But then after drying and some chemical
4 treatment, starts curling up, while tissue stays
5 flat.

6 Q. Okay.

7 A. Curling up or moving, I mean curls
8 up, lifts up, and then starts floating around.

9 Q. What are you going to say at trial
10 about Figure Set 1b on page 20?

11 A. Just an example of foreign body
12 type inflammatory reaction.

13 Q. Okay. Let's go to page 21.

14 A. Yes.

15 Q. Page 21 is Figure Set 1c:

16 "Foreign body inflammatory
17 reaction, H&E 40X, image of
18 additional TVT cases."

19 Now, I think you told us before that
20 these are previous TVT and TVT-O cases?

21 A. Yes.

22 Q. Do you know whether this is a TVT
23 or a TVT-O?

24 A. No.

25 Q. Can you tell me today whether this

1 slide comes from the set of 22 patients that you
2 received from Dr. Kreutzer?

3 MR. ORENT: Objection.

4 THE WITNESS: My recollection is it was
5 later, one of the later cases.

6 BY MR. THOMAS:

7 Q. Do you know which one it is?

8 A. I can probably trace it but...

9 Q. Is it a medical-legal case?

10 A. I think so, but again it would be
11 hard for me -- just what I recall, it is a TVT that
12 I kept track quite well, TVT or TVT-O.

13 Q. If I asked you to, could you tell
14 me where it came from?

15 A. I can make an effort to figure it
16 out.

17 Q. Okay.

18 A. If I can't, I can't.

19 Q. I'm going to want to know where
20 all these came from. That's what we asked for in
21 advance and I understand we don't have it today?

22 A. I never had the purpose to trace
23 individual cases unless it's for a specific -- the
24 report is prepared for a specific patient.

25 Q. Okay.

1 A. Because of it wasn't my purpose.
2 My purpose was to collect information and
3 photographs for TVT or TVT-O as device. That's why
4 I have difficulty tracing all of them back. Some
5 of them can be traced; some of them cannot.

6 Q. If you look at Figure Set 1c, top
7 left, again, you see the blue polypropylene,
8 correct?

9 A. Yes, I do. And the other hole
10 above it may still contain polypropylene but it's
11 clear because the way it's done two fibers are
12 combined together.

13 One filament is blue, one filament is
14 clear. And they go through the knitting product
15 together, this pair.

16 Q. Does the fact that the hole that
17 you just identified above the presence of blue
18 polypropylene has an irregular shape, does that
19 impact your opinion as to whether the polypropylene
20 is present or not?

21 A. Not irregular. It's more regular
22 curvilinear shape, and there is inflammation around
23 it, so there are several features which tell me
24 that this is space where polypropylene either still
25 is or used to be.

1 If I had polarized light or if I had
2 microscope right now and it would be in the
3 microscope, I could flip polarized light and see.

4 Q. Now, is that tissue that is in
5 that large white area above the polypropylene?

6 A. It is a small fragment of tissue.

7 Q. Is that part of a microtoming
8 artifact?

9 MR. ORENT: Objection.

10 THE WITNESS: Microtomy or processing,
11 it's hard to say, but it's an artifact. It's
12 displaced.

13 BY MR. THOMAS:

14 Q. As you look down to the piece of
15 polypropylene in set 1c, on the top of that blue
16 portion it appears to be some tissue?

17 A. Yes.

18 Q. And that tissue looks to fit right
19 into the tissue above it?

20 A. That's correct.

21 Q. So that's pulled away from the
22 tissue as a part of the microtoming process,
23 correct?

24 MR. ORENT: Objection.

25 THE WITNESS: You have good eyes.

1 BY MR. THOMAS:

2 Q. Why don't I see any bark on that
3 polypropylene?

4 A. Two reasons. Not enough
5 resolution of the picture, and second, not in
6 focus.

7 Q. And do you know how long this mesh
8 was implanted in the person?

9 A. No, I don't remember.

10 Q. But you have those records?

11 A. Most likely. But again, some
12 patient samples came without much records. Most of
13 the samples I received had implantation dates.

14 Q. So what is remarkable about the
15 slides in Figure Set 1c which you'll talk to the
16 jury about?

17 A. It shows a blue fiber. It shows
18 that some of the fibers are blue, but otherwise it
19 shows exactly the same feature as before.

20 It's kind of onion skin mesh fiber
21 covered by inflammation, and then outside of that
22 everything is encapsulated in scar tissue.

23 Q. And the scar tissue would be
24 reflected in your notations in the ones on the
25 right?

1 A. Yes, sometimes I do that.

2 Q. Okay. Anything else remarkable
3 about the figures on page 21?

4 A. No.

5 Q. Let's go to page 22, Figure Set
6 2a. Again, this is images of additional TVT cases.
7 And these would be cases that were not part of the
8 consolidated group that you've just reviewed,
9 correct?

10 A. That is correct.

11 Q. And can you tell me by looking at
12 this whether it was part of the set of cases that
13 you received from Dr. Kreutzer?

14 A. No, that was later case.

15 Q. How can you tell me that? How do
16 you know that?

17 A. Quality of the picture. I see it
18 was not taken with the camera that I had at the
19 time that I received the, those specimens.

20 Q. Was this taken from an active
21 medical-legal case involving Ethicon?

22 MR. ORENT: Objection to the form.

23 THE WITNESS: I don't remember. Most
24 likely it is.

25

1 BY MR. THOMAS:

2 Q. But you can't tell me today what
3 it might be?

4 A. It's hard to say.

5 Q. And what is remarkable about the
6 image in Figure Set 2a on page 22 for purposes of
7 the jury?

8 A. Can I have a pen?

9 Q. I'll give you a blue pen.

10 A. Remember, earlier you asked me
11 about why you cannot see bark? Now you can see the
12 bark, so this is the bark. Right there.

13 Q. What you've indicated is on the
14 left?

15 A. This is the bark right there.
16 This is the bark right there.

17 Q. Now are you assuming for purposes
18 of that statement that polypropylene is still
19 present in that slide?

20 A. Well, degraded part of the
21 polypropylene is still present for sure, because I
22 can see it stained. If the core remains unlocked,
23 there's a different question. In this area, most
24 likely it is.

25 Q. You say most likely it is?

1 A. Because this bark layer is free in
2 the space, and doesn't happen that often. Because
3 if it was free in this area, it would flow all the
4 way. So the way it remains in the tissue it
5 remains attached to tissue.

6 So the bark which is firmly attached to
7 tissue like in this area is most likely detached.
8 So there is no fiber core in this area. But in
9 this specific area, I suspect the core of the fiber
10 is still there.

11 Q. Let me do something so the record
12 is clear.

13 You've made some arrows on Figure 2 A,
14 on the upper image, and there's two arrows on the
15 upper left-hand portion and you suggest that
16 indicates bark -- you suggest that indicates bark,
17 correct?

18 A. I didn't suggest. I just pointed
19 where it is.

20 Q. Okay, fine. And then down in the
21 lower right-hand corner, you've drawn several
22 diagonal lines in addition to two arrows.

23 The two arrows indicate bark, as you
24 understand it, and you believe that the diagonal
25 lines represent polypropylene which is present in

1 the slide, correct?

2 A. Most likely.

3 Q. Okay. Now, we requested that all
4 of the slides that were used in your report be
5 forwarded to our pathologist for their review.

6 Was this slide forwarded to them, to
7 your knowledge?

8 MR. ORENT: Objection.

9 THE WITNESS: No, it's an additional
10 case.

11 BY MR. THOMAS:

12 Q. Okay.

13 MR. ORENT: By the way, just for the
14 record, we have not received any slides from your
15 pathologist either and we have requested that
16 repeatedly.

17 MR. THOMAS: We don't have any to give
18 you. We're working from the same set of slides.

19 MR. ORENT: So you're using the
20 plaintiff's stained slides --

21 MR. THOMAS: So far we have. We figure
22 it's better off using one set of slides. And to
23 the extent we make any, you will have them
24 promptly.

25 THE WITNESS: If it was a litigation

1 case, you have the report.

2 BY MR. THOMAS:

3 Q. Are you familiar with whole slide
4 imaging?

5 A. Yes, I am.

6 Q. Do you do whole slide imaging of
7 these cases?

8 A. Yes, I do.

9 Q. So you have --

10 A. Not for all of them. For some
11 cases, especially the later ones.

12 Q. Okay. And who maintains your
13 whole slide imaging equipment; who has that? St.
14 Michael's?

15 A. Yes, St. Michael's. It's standard
16 equipment.

17 Q. Do you have to pay St. Michael's
18 for use of the whole slide imaging equipment?

19 A. No.

20 Q. Okay.

21 A. It's free for researchers.

22 Q. What kind of machine do they have?

23 A. Aperio.

24 Q. So, you could supply to us digital
25 images of the slides that you have on whole slide

1 imaging, correct?

2 A. As long as you're entitled to
3 receive material or information about the case.

4 Q. Okay. What else is remarkable
5 about Figure Set 2a on page 22?

6 A. Oh, it is a very nice example,
7 again of this layering, onion skinning.

8 The mesh fibers are surrounded by halo
9 of foreign body reaction and everything is encased
10 in solid scar plate.

11 And then normal tissue is beyond the
12 solid scar plate so it is a good example of how it
13 happens.

14 Q. And in terms of -- you've told me
15 that on the upper left of the area where you had
16 the arrows, there's likely not polypropylene but in
17 the lower right there likely is polypropylene?

18 A. Yes.

19 Q. How about in the white area to the
20 right where you've written; can you tell whether
21 polypropylene is present or not?

22 A. Not without polarized light.

23 MR. ORENT: Counsel, we've been going
24 about another hour. Shall we take a short break?

25 MR. THOMAS: Good time, yes.

1 -- RECESS AT 11:27 --

2 -- UPON RESUMING AT 11:44 --

3 BY MR. THOMAS:

4 Q. Doctor, going back to image 2a on
5 page 22 of your report, you described this scar
6 area in your testimony, and then showed how the
7 scar then changed to normal tissue, correct?

8 A. That' is correct.

9 Q. How thick is the area between what
10 you show to be the polypropylene mesh and the scar
11 to the normal tissue? How thick is that area
12 between the polypropylene and the normal tissue?

13 A. You mean in this specific image or
14 in general?

15 Q. In this image.

16 A. It depends on which part of the
17 mesh. The thinnest part is within the hundred
18 microns. The thickest part can be as thick as
19 couple of millimeters, if we measure the whole
20 thing like this.

21 Q. And just for the record, when you
22 say within a hundred microns, you're referring to
23 the area on the left side of the lower image in the
24 yellow, through the scar to the normal tissue. And
25 when you're referring to the couple of millimeters,

1 you were referring to normal tissue to normal
2 tissue in between the two mesh fibers; is that
3 fair?

4 MR. ORENT: Objection.

5 THE WITNESS: That's correct.

6 BY MR. THOMAS:

7 Q. And similarly, down below on the
8 lower left, where you show the polypropylene mesh,
9 you show scar and then you do show normal tissue;
10 how far is it from the polypropylene to the normal
11 tissue; how wide is the scar band?

12 A. The same, within 100 microns.
13 Sometimes you have normal tissue pushing into the
14 pores, sometimes not. Sometimes the scar plate is
15 within a hundred microns -- I mean, the scar
16 capsule. Sometimes it goes to the millimeters,
17 three, four millimeters, it depends.

18 Q. Okay. Anything else remarkable
19 about the images on page 22?

20 A. No, we discussed everything, I
21 think.

22 MR. ORENT: Objection.

23 BY MR. THOMAS:

24 Q. Let's go to page 23 please, Figure
25 Set 2b. Let's talk about this a little bit.

1 Where does this come from?

2 A. It came from, if I remember
3 correctly, Edwards case. If I remember correctly.

4 Q. What is it about this that makes
5 you think it's the Edwards case?

6 A. It is an old photograph.

7 Q. And in the top, on the right-hand
8 side of the image, it looks like a piece of blue
9 polypropylene that's displaced in its location; is
10 that fair?

11 A. Slightly displaced, most of it
12 sits right there, it was in vivo.

13 Q. The other blue pieces that appear
14 there other than the -- why don't you just mark
15 that with an "X" for me so it's clear what we're
16 talking about.

17 A. (Witness complies).

18 Q. There are other blue pieces
19 throughout that image, is that polypropylene or is
20 that stain?

21 A. You mean the blue areas here?

22 Q. Yes.

23 A. Some of it is probably displaced
24 polypropylene, it's hard to say because of the
25 resolution. It could just be inflammation because

1 there is a weird color coming into the pictures.

2 Q. If the blue that appears there is
3 in fact displaced polypropylene, then that's part
4 of the microtoming artifact; is that fair?

5 A. Yes, that's fair.

6 Q. All right.

7 A. Anywhere where cross-section of
8 the fiber overlaps with tissue, is a displacement.

9 Q. All right. And you title this,
10 "Fibrous Bridging and Scar Encapsulation". And
11 it's four times power. What does this show?

12 A. All pores in this section of the
13 mesh are filled with scar tissue. So normal tissue
14 is beyond the scar plate, and all the pores are in
15 the spaces in between, and mesh walls are filled
16 with scar tissue.

17 Q. Okay. The magnification of the
18 image on the prior page is five times this
19 magnification, correct?

20 A. About, yes.

21 Q. Okay. And can you tell me by
22 looking at the image on page 23 in the cluster of
23 four circles, how close it is from the
24 polypropylene across the scar tissue to the normal
25 tissue?

1 A. In this area?

2 Q. Yes.

3 A. It would be within the 100 microns
4 or so.

5 Q. Mark that -- good.

6 A. (Witness complies).

7 In this case, it's thicker, could be as
8 thick as 200 microns.

9 Q. Okay.

10 A. It could be .2 millimeters,
11 roughly.

12 Q. If you wanted to measure that on
13 the slides that you have, can that be done?

14 A. With a eyepiece micrometer, yes.

15 Q. Anything else remarkable about
16 Figure 2b other than showing the scar?

17 A. Fiber bridging, and completely
18 encapsulating the entire structure of mesh pores
19 that fill the scar tissue, and normal tissue is
20 outside. This is the mesh scar complex, or mesh
21 scar plate.

22 Q. As you look at this image, is this
23 a complete slide?

24 A. No, there is tissue beyond
25 slightly. And this end, I think is here on the

1 next page, page 24.

2 Q. Okay. We'll come to that in a
3 second.

4 A. That's my recollection.

5 Q. The figure on 2a, page 22, is
6 obviously a smaller part of a bigger slide, correct?

7 A. That's correct.

8 Q. And you believe that the image on
9 page 23 is also a smaller part of a bigger slide?

10 A. I think most of the mesh is here
11 on the slide --

12 Q. Um-hum.

13 A. -- so there's not much mesh
14 beyond.

15 Q. That's why I'm asking the
16 question.

17 Does the image that's shown on page 23
18 represent the outer boundaries of the mesh in that
19 slide?

20 A. I think so.

21 Q. Okay.

22 A. I think so, there's an edge of
23 tissue here. Now, this exactly piece of this --

24 Q. You've now turned the page, you're
25 on page 24. So you believe this is probably from

1 the Edwards case, your best recollection?

2 A. Yes.

3 Q. And it's magnified ten times, and
4 this is the one that is a magnification of the far
5 right side of the image on page 23?

6 A. Likely at different level.

7 Q. What do you mean, a different
8 slide?

9 A. Different slide, yes.

10 Q. Okay.

11 A. So it's the same piece, but cut
12 little deeper.

13 Q. Now if you look on the top page of
14 page 24, top image, on the right side there's a
15 blue, that's again, displaced polypropylene?

16 A. Yes, this is displaced
17 polypropylene. And this as well (indicating).

18 Q. Okay. And that's an artifact due
19 to the microtoming process?

20 A. It could've done that, yes.

21 Q. And the description down below
22 again is "fibrous bridging and scar encapsulation",
23 does this image show anything in addition to what
24 we've talked about in the prior slides?

25 A. This is a terminal pore.

1 Q. Sorry?

2 A. This is a terminal pore of the
3 mesh. So this is the edge of the mesh and the
4 terminal pore contains normal non-scar tissue.

5 Q. When you say "terminal pore"
6 that's the outside pore?

7 A. Yes, it is.

8 Q. So what is the significance of the
9 terminal pore having normal tissue?

10 A. It just shows comparison. Pores
11 which are not filled with scar tissue, and pores
12 which are filled with scar tissue. So this
13 specific pore contained normal scar tissue. So
14 within that specific pore, there's no fibrous
15 bridging.

16 Q. Is it fair to say every place we
17 see the blue, we see displaced polypropylene?

18 A. Most of the time. It can be just
19 a weird color of inflammation.

20 Q. Okay. Anything else remarkable
21 about the slide on page 24?

22 A. No.

23 Q. Okay. Let's go to page 25.

24 A. Yes.

25 Q. This is cited to an article. Do

1 you know off the top of your head what article that
2 is?

3 A. On the safety of synthetic sling
4 surgery, I believe.

5 Q. Are you able to tell me what slide
6 that is, what plaintiff? Strike that.

7 Is that a medical-legal slide?

8 A. The picture comes from the same
9 case, as you can see it's exactly the same.

10 Q. Okay. Is B part of A?

11 A. No, I don't believe so.

12 Q. Let's talk about A. And what does
13 the "BF" mean?

14 A. "Bridging fibrosis".

15 Q. And the "AT"?

16 "Adipose tissue"?

17 A. Adipose tissue, yes.

18 Q. What is the significance of the
19 adipose tissue?

20 A. It's a normal non-scar tissue.

21 Q. So what is the significance of
22 including this slide in your report if it's the
23 same thing that you had in the prior two slides?

24 A. It's a little bit different.

25 Because, see, on the bottom, B, it shows scar

1 tissue in a different stain.

2 Scar tissue may have some smooth
3 muscle, when the scar tissue is being remodeled by
4 myofibroblast. Myofibroblast can have smooth
5 muscle. But once it's mature scar tissue, there is
6 no contractile filament in the cells anymore, and
7 it doesn't stain with smooth muscles stain.

8 But, normal tissue of vaginal wall
9 contains smooth muscle. So here you can see that
10 the fibers bridging, can be separated from normal
11 tissue by using smooth muscle stain.

12 Q. And so the smooth muscle, or the
13 normal tissue is represented by the brown?

14 A. Yes.

15 Q. And this is another representation
16 of the fibrous bridging and scar encapsulations
17 depicted in blue?

18 A. Yes.

19 Q. Is that the only significance of
20 that stain?

21 A. Yes.

22 Q. Okay.

23 A. For this specific picture, yes, it
24 is.

25 Q. All right. Are you able to tell

1 me the magnification of that image?

2 A. Close to times four maybe --
3 because there's cropping and then the size was --
4 now it's hard to -- it's much larger than it
5 appears in the publication. So I would say for
6 this specific, it would be close to times four
7 objective.

8 Q. If you go down here it says:

9 "Scar encapsulating mesh in
10 surrounding pre-existent normal
11 adipose tissue and muscle tissues, a
12 2.5 image of histological sections."
13 That means it's magnified 2.5 times.

14 A. It means that the objective you
15 would use to produce this appearance in the
16 microscope, this would be times 2.5.

17 Q. Okay. But the degree of
18 magnification is different from that?

19 A. On this page?

20 Q. Yes.

21 A. Yes. Because it's cropped and
22 resized and the publication is much smaller.

23 Q. I see.

24 A. So if you trace it, if more
25 correctly to trace it, to trace is the objective,

1 you would use to see like this in the microscope.

2 Q. And you could use the optical
3 micrometer in order to measure to the extent
4 necessary?

5 A. Yes, I can.

6 Q. Anything else about this image?

7 A. No.

8 Q. Let's go to page 26, image 3a.

9 A. Yes.

10 Q. What's the purpose of this image?

11 A. This image shows the nerve in H&E
12 stain.

13 Q. What is the significance of
14 showing the nerve; just the fact that you can show
15 it? Is there any damage to it or any issues
16 associated with it?

17 A. It's normal nerve, it's present
18 within this mesh scar plate, it innervates the
19 tissue which is inside and outside of the mesh. It
20 can become trapped.

21 Q. Is it trapped in this image?

22 A. Well, it is in scar tissue. So
23 it's trapped in scar tissue.

24 Q. Is there any indication that this
25 nerve is damaged in this image?

1 A. Not from this power, I don't see
2 any -- "damage", you mean atrophic degenerated or
3 damaged in terms of physical damage?

4 Q. Any kind of damage.

5 A. It is in scar tissue. For a nerve
6 to be in scar tissue, is not a healthy environment.

7 Q. But not all nerves in scar tissue
8 produce symptoms, correct?

9 A. Not all.

10 Q. And you can't tell by looking at
11 this image, whether the nerve in Figure Set 3a is
12 producing any symptoms, correct?

13 A. Again, it depends on timing. It
14 may produce symptoms at one time and not produce at
15 another time.

16 If this specific nerve was producing
17 pain sensation, it would be difficult to determine.

18 Q. But you can't tell, looking at the
19 nerve in Figure Set 3a, whether that nerve is
20 producing symptoms for this patient, correct?

21 A. I can tell you that this nerve is
22 in a situation when it can produce symptom. This
23 is the main thing I can say, it can because it is
24 in an abnormal environment.

25 Q. And the abnormal environment is

1 the presence in the scar tissue?

2 A. Yes. In addition to be present
3 inside the mesh.

4 Q. Okay. Well, it's adjacent to the
5 mesh, correct?

6 A. I don't know. There might be
7 fiber right there.

8 Q. Okay.

9 A. So it can be inside or outside, it
10 doesn't matter. It's in scar tissue, it's abnormal
11 environment, it can produce mesh. And we know that
12 traumatic neuromas, which is the formation of a
13 mesh in scar tissue, is a painful lesion. This is
14 an established fact.

15 Q. But there's no traumatic neuroma
16 in this image, correct?

17 A. A mesh is deformed, we can see
18 it's getting there.

19 Q. Can you see a traumatic neuroma in
20 this image, 3a on page 26?

21 A. The formation is not significant
22 to call it a traumatic neuroma. So in this
23 specific image, I would not use that term.

24 Q. Now, can you tell whether the
25 nerve on page 26 that you show is a motor nerve?

1 A. It's a mixed nerve.

2 Q. What do you mean by "mixed nerve"?

3 A. "Mixed" means they're both
4 afferent and efferent, or motor and sensory signals
5 going back and forth.

6 Q. How can you tell it does both? Do
7 all nerves do both?

8 A. Peripheral nerves, yes.

9 Q. All of them?

10 A. Except for head.

11 Q. Okay. So are all nerves in the
12 body, peripheral nerves, capable of mediating pain?

13 A. Except for cranial nerves.

14 Q. Okay. And what's the basis for
15 your understanding in that regard?

16 A. It's a basic knowledge, it's in
17 the textbooks.

18 Q. Okay.

19 A. There is some very small
20 proportion of nerves, peripheral nerves, less than
21 5 percent, which are only sensory. So some of the
22 nerves will be only sensory. But there are almost
23 no, only motor nerves outside of the cranial
24 nerves.

25 Q. Can you, by light microscopy,

1 distinguish among the type of nerves which you see?

2 A. What do you mean, what type of
3 nerves?

4 Q. Well, sensory and motor nerves?

5 A. We just agreed that they're all
6 mixed.

7 Q. You said that, okay.

8 Is there any way for you to distinguish
9 by light microscopy which nerves are capable of
10 mediating pain?

11 A. They all are.

12 Q. Okay. 5 percent you said, where
13 are they?

14 A. 5 percent is still sensory. So
15 all of them can deliver pain. Some of them,
16 5 percent, may not be able to do any motor
17 function, but they will still be able to transmit
18 pain. And it also depends on the size, because
19 once you go into the very small branches, they
20 become more specialized. If you go into the large
21 trunk, then you get all of them mixed together.

22 Q. When you talk about going into the
23 nerve twigs, that's what you're talking about,
24 right?

25 A. Fibers, individual fibers, yes.

1 Q. Then they become more specialized;
2 what do you mean by that?

3 A. So they may have more function for
4 sensory or motor function.

5 Q. So as the nerves break into twigs,
6 will there be some nerves that don't mediate pain,
7 or they still mediate pain?

8 A. Fibers. If you go into fibers
9 which is even smaller than twigs, which is
10 individual axon, those will have individual
11 function.

12 Q. And what are we looking at nerves
13 here; are we looking at twigs, fibers, or are we
14 looking at nerves?

15 A. It's a nerve. It's thicker than a
16 twig.

17 Q. Okay. And what is remarkable
18 about what you see in Figure 3a; anything more than
19 you've just described, the presence of a nerve
20 adjacent to mesh?

21 A. No, just everything else -- we
22 discussed everything significant.

23 Q. Now, the polypropylene in the
24 lower left-hand corner image, that's blue
25 polypropylene, correct?

1 A. That's correct.

2 Q. And it's folded over as a part of
3 the sample preparation process or microtoming
4 process, correct?

5 A. That's correct.

6 Q. This is a 4 micron thick slide,
7 correct?

8 A. About 4 microns, plus or minus.

9 Q. I don't see bark on that
10 polypropylene. Do you see any bark on the
11 polypropylene?

12 A. There is a faint line here, I
13 don't know if it's there or not.

14 Q. When you say "there," you're not
15 pointing to the polypropylene. You're pointing to
16 the circular area to the left of the polypropylene
17 adjacent to the tissue, correct?

18 A. Yeah. Curving linear, yes.

19 Q. And you're suggesting that that
20 may be some bark?

21 A. Yes.

22 Q. And why do you say that?

23 A. Because it looks like it.

24 Q. Okay. And this is magnified at 20
25 times?

1 A. Yes. For this specific image,
2 about 20 times -- 20 times objective magnification.

3 The magnification itself is higher,
4 because there's also an eyepiece, but eyepiece is
5 fixed.

6 Q. Look at the right side of that
7 image with the polypropylene. It's folded over, on
8 the right side; you'd agree with me there is no
9 bark?

10 A. Not visible bark.

11 Q. Okay. If we go to page 27, set
12 3b.

13 So 3a comes from the images from the
14 consolidated cases, correct?

15 A. That is correct.

16 Q. So we should have this slide, I
17 think. So paragraph 3b, so set 3b on page 27 says,
18 "additional TVT cases".

19 Are you able to tell me from which case
20 this slide comes?

21 A. I can only tell you that the top
22 panel is from a newer case, and the bottom is
23 likely from an older case.

24 Q. So they're two separate cases?

25 A. Yes.

1 Q. Do you have any idea from looking
2 at this, how long the mesh was implanted in these
3 people?

4 A. No. Not at this magnification.

5 Q. And other than showing the
6 presence of nerves within the mesh scar plate like
7 you did on page 26, is there anything significant
8 about your findings on page 27?

9 A. The only difference is that in top
10 panel, you can clearly see that this nerve is
11 within the pore.

12 Q. Are you suggesting that this nerve
13 is inside of a single pore in the mesh?

14 A. Somewhere within the mesh.

15 Q. Okay. Not within the pore itself?

16 A. It can be within the pore.

17 Q. Do you know?

18 A. It also depends how you define the
19 pore. Pore is a hole in the mesh structure, yes,
20 it is within the space in the mesh structure.

21 Q. This is 20 times magnification,
22 how far is it from one yellow to the other yellow?

23 A. At 1.5 millimeter. Between 1 and
24 1.5 millimeter.

25 Q. Is there anything abnormal about

1 the nerve that's depicted on page 27 in the top
2 frame?

3 A. It's in the scar and it's in the
4 mesh, that is abnormal.

5 Q. Other than being in the scar
6 plate, is there anything you can tell by light
7 microscopy about abnormality in that nerve?

8 A. Otherwise, the nerve looks
9 healthy, it would conduct pretty healthy pain
10 signals.

11 Q. Okay. Same thing for the lower
12 frame. Other than the presence of the nerve within
13 the scar tissue, is there anything that you can
14 tell from light microscopy about the general health
15 of the nerve?

16 A. Same thing, it's not degenerated,
17 therefore, it can conduct pain signal.

18 Q. As you look at the image on the
19 lower left on 3b, the white in that image, again,
20 is where polypropylene was?

21 A. Yes.

22 Q. And as you come down around from
23 about 6 o'clock to about 9 o'clock, there's no bark
24 there, is there?

25 A. No. I don't think so.

1 Q. Let's go to page 28. Page 28 is
2 additional TVT cases.

3 Is this one mesh or two? One patient
4 or two, I guess I should say.

5 A. This is hard to say, both are come
6 from earlier cases. I probably have thousands of
7 images by now, so it will be hard.

8 Q. But you can't tell me from which
9 patient they come, or which case they're from?

10 A. I may or may not be able. It
11 would be checking if it's in a specific folder or
12 just in pooled images.

13 Q. And your description again, below
14 is, "Innervation within the mesh scar plate, H&E,
15 20 times magnification."

16 Other than showing the presence of
17 these nerves in the mesh scar plate, is there
18 anything that indicates to you by light microscopy
19 that these nerves are unhealthy?

20 A. Well, it's the location. You see,
21 it's slightly curved, it's inside the pore.

22 Q. Which one are you talking about
23 now, please?

24 A. The upper panel.

25 Q. Okay, thank you.

1 A. There are two nerves, one is here,
2 one is there (indicating).

3 Q. And you indicate that with your
4 two arrows --

5 A. This one is gone.

6 Q. Okay.

7 A. So it is a location -- it's not
8 the nerve itself, it's the location is abnormal.

9 Q. Is there anything that you can
10 tell me by looking at this image by light
11 microscopy that these nerves were producing
12 symptoms in the patient?

13 A. The question is, if they can.

14 Q. Can you tell me by looking at this
15 image in set 3c, that these nerves are causing
16 symptoms in the patient?

17 MR. ORENT: Objection.

18 THE WITNESS: Again, as a pathologist,
19 I can only estimate the probability. If it can, if
20 it's in abnormal location, if it's causing a lot --
21 first of all, it's out of the body now, so it
22 cannot cause anything. But when it was in the
23 patient, it could.

24 BY MR. THOMAS:

25 Q. Could?

1 A. Could produce symptoms all the
2 time, or one specific time, or only once in a
3 specific moment, it's hard to say.

4 Q. And it could be a nerve positioned
5 as it is, that never produced any symptoms, true?

6 MR. ORENT: Objection.

7 THE WITNESS: Some of them probably not
8 producing anything.

9 BY MR. THOMAS:

10 Q. Okay. And the same thing about
11 the image below on Figure Set 3c on page 28, other
12 than presence of the nerves in the mesh scar plate,
13 anything remarkable about this image?

14 A. No. Nothing beyond what we've
15 discussed.

16 Q. Let's go to page 29.

17 A. Yes.

18 Q. What are we showing on page 29?

19 A. The same features of innervation
20 of the mesh scar plate. But now in S100 stain.

21 Q. Now, is there anything other than
22 presence of these nerves in the mesh scar plate
23 that indicates to you that these nerves were
24 causing pain in the patient?

25 A. They are in abnormal location.

1 Q. And we've already agreed that
2 nerves, even in an abnormal location, may not be
3 producing pain, correct?

4 A. Yes, but more likely they will
5 produce pain.

6 Q. Are you saying that every nerve
7 within the mesh scar plate more likely than not is
8 going to cause pain?

9 A. Through one mechanism or the
10 other, there will be zero mechanism at one point
11 that can produce pain, it may not be chronic pain
12 continuous, but I mean, in a specific movement you
13 have start forming the mesh, so it can cause pain.

14 Q. Let's talk about this for a
15 minute. Doctor, if you look at page 29, and 28,
16 and 27 and 26 --

17 A. Yes?

18 Q. -- it's fair to understand that
19 for every mesh implantation, there are going to be
20 nerves that are going to be in scar tissue.

21 A. Are you talking for all meshes?
22 Regardless of location, or just --

23 Q. I'm talking about slings. Stress
24 urinary incontinence slings, TVT, Prolene.

25 A. So for slings, there will be

1 innervation, at least those samples I examined,
2 there will be innervation in all of them.

3 Q. Okay. And complaints of pain for
4 slings, TVT slings, you'll agree is less than 5
5 percent?

6 MR. ORENT: Objection.

7 THE WITNESS: For the specimens I
8 received?

9 BY MR. THOMAS:

10 Q. I'm talking about the studies on
11 the topic?

12 MR. ORENT: Objection. Outside the
13 scope.

14 THE WITNESS: Now we're talking about
15 what I received and what is still in the patients.
16 Because studies were clinically done based on
17 clinical -- clinical symptoms for the samples or
18 slings which are still in the body.

19 BY MR. THOMAS:

20 Q. Very simple question.

21 How do you explain findings in the
22 clinical studies that pain is a complaint of
23 patients in less than 5 percent of the time, when
24 you say in every mesh that you see, that there are
25 nerves within the scar plate?

1 A. Well, first of all, let's start
2 with 5 percent.

3 That number would have to be specific
4 for our study. There is a range of reported pain
5 anywhere from 5 to 40 plus percent. It depend on
6 methodology, if the patients were followed in time
7 correctly, if there was correctly of follow up
8 time. So the 5 percent is a questionable number.

9 Q. Can I interrupt you there, if you
10 don't mind. Let's take your upper bound of
11 40 percent?

12 A. Yes.

13 Q. So you have, by your own
14 statement, even in the worse case scenario, you
15 have 60 percent of the sling patients who don't
16 experience pain, correct?

17 A. Who do not complain to the point
18 when it's recorded.

19 There are multiple reasons why it may
20 not be recorded, they may still experience some
21 pain. Maybe it's not serious enough to be
22 recorded, maybe it's not serious enough -- there
23 will be some patients which have no pain at all.
24 There will be some patients which have so little
25 pain, only in a specific moment, that it's not

1 worth reporting. Some of them don't report it and
2 so forth.

3 And then there will be patients that
4 there is so severe pain, the mesh needs to come
5 out. There will be a range of sensations and
6 personal perception.

7 So, from my perspective, when I examine
8 specimens, I report what is abnormal. To what
9 degree it's causing clinical symptoms, it depends
10 on many factors. If you want to -- you cannot look
11 at the human body as a machine. I mean, there is
12 part missing, it's not going to work. Or if there
13 is wire loose, I mean, it may cause some problems.

14 So, there will be a range of -- or
15 degree of pain sensation and a range of personal
16 attitude so this will effect the recording of
17 clinical symptoms.

18 On the histology side, again, there
19 will be a range of how many nerves are involved,
20 one or two, or a really high density. To what
21 degree they are involved, some of them will have
22 such a strong deformation, that there is
23 100 percent probability that it will cause pain.

24 Q. Let me ask this question --

25 A. So that's the complexity of the

1 situation. I mean you cannot separate it sharply,
2 okay, 5 percent for this, 5 percent for that. It
3 can cause a pain. This is abnormal location, this
4 is abnormal situation, this is a pathological
5 finding.

6 Q. Let's talk about this for a
7 minute. So the pages we've just been through,
8 we've talked about, on pages 26, 27, 28 and 29, and
9 it goes on to 30 and 31, and on to 33. But just
10 for those for now.

11 Is it fair to understand that in every
12 mesh that you've analyzed - regardless of
13 manufacturer - in the pelvic floor, for treatment
14 of stress urinary incontinence, you find nerves in
15 scar tissue?

16 A. Yes.

17 Q. Okay.

18 A. The degree of innervation will be
19 different, there will be a degree of also nerve
20 deformation within the mesh, but strictly saying
21 there will be innervation of the scar plate in
22 almost all patients.

23 Q. Have you made any attempt to
24 differentiate across manufacturers, the extent to
25 which the innervation of the scar plate varies?

1 A. No.

2 Q. Have you made any attempt to
3 differentiate across types of mesh products, the
4 extent to which nerve innervation varies?

5 A. I may in the future, I haven't
6 done it yet. But I may in the future.

7 Q. Okay. So is it fair for me to
8 understand, and the record to reflect, that for
9 every mesh implanted for the treatment of stress
10 urinary incontinence, it's your opinion that there
11 will be nerve innervation within scar plate, that
12 you think is capable of causing pain?

13 MR. ORENT: Objection. I think his
14 testimony is every mesh that he's looked at.
15 Manufactured, that he's looked at.

16 I don't think Dr. Iakovlev has any
17 opinions about mesh he's never looked at, brands
18 he's never looked.

19 THE WITNESS: Yeah, that's correct.

20 BY MR. THOMAS:

21 Q. Okay. Let me ask you this question --

22 A. Let's repeat the question, then I
23 can answer it in more...

24 MR. THOMAS: Would you read it back,
25 please?

1 -- REPORTER'S NOTE: Question read as
2 recorded above.

3 THE WITNESS: Oh, as I said, I can only
4 testify or make opinions of what came out of the
5 specimen. And I told you earlier, that there is --
6 I have been dealing with those specimens which
7 caused complications already.

8 BY MR. THOMAS:

9 Q. For every mesh sample that you've
10 looked at for mesh use for the treatment of stress
11 urinary incontinence, have you found mesh
12 innervation in the scar tissue?

13 A. Almost all, yes.

14 Q. Any you haven't?

15 A. If it was a small sample, maybe
16 one or two, I couldn't find nerves.

17 Q. Is that because -- do you have an
18 opinion, is that because the sample was too small,
19 because it didn't exist, or do you have an opinion?

20 A. I cannot say beyond that, I just
21 didn't find it. It could be sampling issue, it
22 could be not. Again, I cannot state what I don't
23 know.

24 Q. And how many have you seen?

25 A. Individual cases.

1 Q. How many have you seen?

2 A. Less than five.

3 Q. How many total cases have you
4 seen?

5 A. Oh, from slings?

6 Q. Yes.

7 A. About 100.

8 Q. About 100. And less than five you
9 have not seen nerve innervation within scar tissue?

10 A. Yes.

11 Q. And you don't know whether that's
12 because it is a sampling error or because there
13 wasn't any nerves in the scar plate?

14 A. That's correct.

15 Q. Is it fair to say, based on your
16 experience as a pathologist, that you would expect
17 that when mesh is placed for the treatment of
18 stress urinary incontinence, that nerves would be
19 encapsulated by the scar tissue in the healing
20 process?

21 A. They can. If they become trapped
22 in the scar tissue, each single implanted mesh, we
23 would have to do autopsy series. I cannot go
24 beyond what I see in explanted meshes, and all
25 explanted meshes came out for complications. And

1 almost all of them, or a large proportion had pain
2 as a symptom.

3 Q. Again, the cases you've received
4 have been complications?

5 A. Yes.

6 Q. And of course you know that people
7 have mesh removed for reasons other than pain,
8 don't you?

9 A. In hernia surgery, yes.

10 Q. Do you know whether or not
11 patients have mesh removed for reasons other than
12 pain?

13 MR. ORENT: Objection.

14 THE WITNESS: There might be an
15 overwhelming other complaint, like erosion or
16 infection, but in almost -- I don't want to stick a
17 number, but most of these patients complain of some
18 degree of pain.

19 BY MR. THOMAS:

20 Q. Have you have investigated, as a
21 part of your work in this case, the reasons why
22 patients have mesh removed?

23 A. There's always a reason.

24 Q. I understand that. Do you know
25 what they are, and percentage wise, how they

1 breakout across a patient population?

2 A. You mean the driving reasons for
3 implantation?

4 Q. Yes.

5 A. It's in the paper. At least in
6 those 164 samples.

7 Q. And that's the paper you did with
8 Dr. Blaivas?

9 A. No. The degradation paper.

10 Q. Okay.

11 A. But there's always a driving
12 reason for explantation. There may be driving
13 reason for explantation is erosion, but then pain
14 is attributed to erosion. So it's not indicated as
15 a main reason of explantation.

16 Q. You can have voiding dysfunction?

17 A. Okay. In a voiding dysfunction,
18 but again, voiding dysfunction usually what
19 happens, you have a strong compression against
20 urethra, and this produces pain due to compression.
21 So there will be a mixture of mechanisms for pain.

22 Q. Are you suggesting that voiding
23 dysfunction is subsumed within the pain that's
24 reported in these studies?

25 MR. ORENT: Objection.

1 THE WITNESS: No, it's combined. It
2 can be combined, this pain.

3 BY MR. THOMAS:

4 Q. Okay.

5 A. To cause void and dysfunction,
6 even to compress urethra to a degree that the
7 outflow is obstructed.

8 Q. Are you aware of any studies which
9 have analyzed meshes removed because of pain,
10 compared to meshes removed for other reasons in
11 comparing the histology of those meshes?

12 A. We're doing some work in hernia
13 specimens.

14 Q. But in terms of published
15 peer-reviewed studies today, are you aware of any
16 studies out there, which compare the histology of
17 meshes removed for pain, and meshes removed for
18 non-pain reasons?

19 A. That's a very good question. Why,
20 after 50 years and a large proportion of specimens
21 removed for pain, there is no histology study. Why
22 has this not been done?

23 Q. So did you do a literature search
24 of that?

25 A. Of course I did.

1 Q. And you didn't find any studies
2 that compared the histology of mesh removed from
3 patients who complained of pain, compared to the
4 histology of patients who had mesh removed for
5 non-pain reasons?

6 A. There were descriptions in hernia
7 publications. I mean in meshes removed for hernia
8 repair.

9 Q. Which studies, do you remember?

10 A. 2005, Klosterhalfen. He put the
11 picture of deformed nerve, and he states that in
12 his experience, over 60 percent of the meshes
13 removed for pain have some degree of nerve
14 involvement.

15 Q. Do you view Dr. Klosterhalfen as
16 authoritative in this area?

17 A. Yes. He's an authority, he's one
18 of the oldest researchers.

19 Q. Do you know whether Dr.
20 Klosterhalfen has ever investigated the precise
21 question about whether the histology of mesh
22 removed for indications of pain is different from
23 the histology of mesh for -- from patients removed
24 for non-pain reasons?

25 A. That's what he stated. Over

1 60 percent of the specimens removed for pain showed
2 nerve involvement.

3 MR. ORENT: Before we go on to the next
4 question, you had cut Dr. Iakovlev off from
5 answering. He started to say "but there are other
6 authors", if you want to just continue.

7 THE WITNESS: Yes. There are other
8 descriptors of meshes removed for pain, and they
9 would find nerve involvement with traumatic
10 neuroma. Those are, I think individual cases, not
11 the series.

12 Again, same histology. They were
13 trying to figure out what was wrong, what was
14 causing pain, and they found nerve involvement.
15 And that was done before I started researching my
16 nerves.

17 BY MR. THOMAS:

18 Q. Would you expect more or less
19 inflammation to be seen in histology of meshes
20 removed for pain than meshes removed for non-pain
21 reasons?

22 A. To a degree. My research in
23 hernia showed that foreign body inflammation is a
24 component of pain mechanism. So those meshes which
25 were removed for pain only, they continue to have

1 relatively steady, pronounced foreign body reaction
2 many years after implantation.

3 And those which were removed for
4 recurrence, they show a trend down. So at the
5 beginning, there is inflammation, then it goes
6 down.

7 So by the time of explantation, if it
8 happens eight years or ten years after
9 explantation, foreign bodies subsided; which is
10 different from those which were removed for pain.

11 Q. So are you able, from your
12 research, in your work, to form an opinion as to
13 whether mesh removed for purposes of pain, the
14 histology will show higher rates of inflammation
15 than the histology for meshes removed for non-pain
16 reasons?

17 A. So before we go into the
18 individual findings, you're trying to split it into
19 what is causing the pain, nerve entrapment and
20 inflammation or something else.

21 This is a complex process. There are
22 multiple factors which are playing, together with
23 patient perception of pain and reporting of pain.

24 So with this type of complexity, we
25 cannot separate one individual feature. Overall,

1 there's a pool, if we collect enough, we can see
2 the difference. For each individual patient, how
3 much of this feature, or that feature is playing a
4 role in each individual symptom, will be very
5 different from patient to patient.

6 So overall, the higher degree of
7 foreign body reaction is associated with higher
8 rates for chronic pain.

9 Q. And that's based on your research
10 or other published research?

11 A. Foreign body has been worked up
12 quite a bit in published histological studies. How
13 much of that was specifically determined, comparing
14 two groups or three groups, it's difficult to say,
15 I don't remember right now.

16 So it is a combination of what was
17 published before, and what I find in my samples, so
18 that's -- that would be a basis for my opinion.

19 Q. Is it your opinion that results in
20 the hernia literature on the issue of association
21 between inflammation and pain, are transferrable to
22 the pelvic floor?

23 A. Some are, yes. Not everything,
24 but some are.

25 Q. Okay. And why would it not be?

1 A. There are different anatomical
2 locations, different physical factors acting on the
3 scar plate. It also crosses many anatomical planes
4 in the pelvis. While in the abdominal wall, and
5 it's parallel to anatomical planes.

6 Q. I'm trying to get through this for
7 a second. If you'll look at pages 30, 31, 32 and
8 33. Are the images on those pages additional
9 depictions of nerves within the mesh scar plate?

10 A. That's correct.

11 Q. Is there anything else significant
12 about those images other than they show innervation
13 within the mesh scar plate?

14 A. No.

15 Q. On page 33, Figure Set 3h, in the
16 upper right-hand corner, you've called out what
17 you've described as a "neurovascular bundle"; what
18 is that?

19 A. Most of the larger nerves in the
20 medium size arteries, become together. One artery,
21 two veins, and one nerve, that's how it works. And
22 the nerve just starts bleeding, so the nerve goes
23 its way and artery goes its own way.

24 So in this specific case, an artery and
25 a nerve are still together.

1 Q. Okay. The brown is the nerve,
2 correct?

3 A. Yes. I mean, there are some other
4 brown, probably picking up some other stuff, but
5 this is --

6 Q. Where is the artery?

7 A. In the blue. You can see
8 streaming, it's not a really high resolution.

9 Q. What is the significance of the
10 neurovascular bundle as depicted in that image?

11 A. Well, see, it is in the tight
12 spot. So this is really as compartmentalized as it
13 gets, and slightly deformed.

14 So if you move this mesh around, the
15 fibers will start compressing on the neurovascular
16 bundle. It may cause obliteration of the artery,
17 or can impinge the nerve.

18 Q. Is there any impingement shown in
19 this image?

20 A. Well, it's deformed.

21 Q. Is there any impingement shown?

22 A. It does, because it's deformed,
23 it's curved.

24 Q. And you're referring now to the
25 lower right-hand image?

1 A. That's correct.

2 Q. Is there anything you can tell by
3 looking at that image, whether that curved nerve
4 was causing pain in this patient?

5 A. I can say the probability of this
6 causing pain is much higher than a nerve which is
7 not deformed. Like something like this on page 31.

8 Q. You can't rule out by looking at
9 the image on page 33, where you show the curved
10 nerve, you can't rule out that that nerve is not
11 causing pain, correct?

12 A. I think we're going back to the
13 same issue. You're taking human body as a machine,
14 it's not. Medicine doesn't happen like that. So
15 there are many, many, many factors which cause.

16 If the same image we put in MRI image,
17 and this deformation would be on the root coming
18 from the back, the radiologist would report that
19 there's impingement of a root. And that's how back
20 pain occurs that's radiating to the leg, and so
21 forth. So this is a much smaller scale, the same
22 mechanism.

23 Q. Do you know whether this patient
24 was complaining of pain?

25 A. Most likely she was.

1 Q. Do you know?

2 MR. ORENT: Objection.

3 THE WITNESS: With 100 percent
4 certainty, no.

5 BY MR. THOMAS:

6 Q. Okay. And you talked about an
7 obliteration of the artery. Does the image on
8 page 33 in the upper right show an obliteration of
9 the artery?

10 A. No, not this image.

11 Q. Other than the nerve impingement
12 that you've described, and the potential for
13 obliteration of the artery, is there anything
14 unusual about the depiction of the nerves in those
15 images?

16 A. No.

17 Q. And I need you to go back, because
18 I didn't ask you that question about the prior two
19 pages, 30 through 32.

20 Other than the depiction of the nerves
21 within the scar plate, is there anything about the
22 nerves that are seen there that cause you any
23 concern about the potential of those nerves to
24 cause injury?

25 MR. ORENT: Objection.

1 THE WITNESS: So going back to
2 mechanisms of pain. So there are two mechanisms,
3 or two major groups of mechanisms to cause pain.
4 First, you affect the nerve itself. So you impinge
5 it, squeeze it, becomes deformed and that can be
6 felt as pain, the nerve itself, the nerve trunk.

7 The second group of mechanisms is when
8 you affect the receptors. And the receptors can be
9 affected, it can be again a mechanical trauma,
10 cutting, compressing, burning, chemical trauma,
11 ischemia, then the receptors are signalling pain
12 through the nerve. So for smaller branches, the
13 significance is that the receptors now can pick up
14 the signal of nerves -- of pain, and then it will
15 be delivered through these branches, so it just
16 shows that this tissue can sense pain.

17 BY MR. THOMAS:

18 Q. Okay. This tissue is capable of
19 sensing pain?

20 A. Yes.

21 Q. Not that it is in fact sensing
22 pain in the body at the time?

23 A. If you have other mechanisms to
24 deliver pain, it will be -- it will be causing
25 pain.

1 Q. Correct.

2 A. Now, if you go to page 33, this
3 will be an example where it would be directly
4 effecting the nerve trunk. Impingement of the
5 nerve.

6 Q. Now, are you able, in these
7 images, 30 to 33, to show me any nerve receptors?

8 A. You mean receptors, nerve endings.
9 When it goes really small, you can see really
10 fiber, and it is -- most of the ends will have no
11 staining, because they just disappear. But I mean,
12 you'd have to go in higher magnification.

13 Q. So with the magnification you have
14 here, you're not able to identify any nerve
15 receptors; is that fair?

16 A. No, not in these pictures. It's
17 too small magnification.

18 Q. I have to ask the question again
19 because you answered "no" to a negative question.

20 It's fair to understand that based on
21 the magnification that you have in these images on
22 pages 30 to 33, you can't identify any nerve
23 receptors, correct?

24 A. I cannot see nerve receptors at
25 this degree of magnification.

1 Q. Thank you.

2 If you go to page 34, what is the
3 significance of this image?

4 A. This shows another severely
5 deformed nerve. So this would be a mechanism for
6 pain through impingement.

7 Q. And the severely deformed nerve as
8 you described it, is the brown portion, stained
9 brown?

10 A. The dark brown portion or dark
11 brown structure.

12 Q. And in the lower left-hand corner,
13 the white area is where the polypropylene is or
14 was, correct?

15 A. That's correct.

16 Q. And what's the significance of the
17 dark blue and the border of that area? Is that the
18 staining mechanism, or does that tell you anything?

19 A. Can you point it? So significance
20 of what?

21 Q. The darker blue.

22 A. This dark blue?

23 Q. Yes.

24 A. That's inflammation.

25 Q. Okay. And the upper is 2.5 power,

1 and the lower one was four times; is that correct?

2 A. It's a typo, it should be 40.

3 Q. 40?

4 A. 40. Somewhere between 40 X and 50 X.

5 Again, the cropping factor there, the magnification
6 there is not exactly...

7 Q. And these are, again, additional
8 TVT cases, and you have not supplied us the slides
9 for these cases, correct?

10 MR. ORENT: Objection.

11 BY MR. THOMAS:

12 Q. In this case?

13 A. That's correct. These are
14 previous TVT cases.

15 Q. On page 35 --

16 A. Yes.

17 Q. -- you suggest degeneration of
18 affected nerves; tell me what you mean by that?

19 A. So you see the inner portion of
20 the nerve lost myelination. So there is
21 degeneration of myelin sheath in the nerves. It
22 means that these nerves cannot deliver, or most
23 likely not deliver irregular signals.

24 So earlier you were asking about the
25 abnormality, this is the abnormality that we're

1 talking about, this is the nerve degeneration. In
2 this case, if this part is sensory, inside, it
3 means that the area is numb.

4 This part of the nerve cannot sense
5 pain or innervation of that part of the body, which
6 goes through this nerve, may not experience any
7 pain; it's numb.

8 Q. And that's the portion you're
9 referring to in the lower right-hand image with the
10 arrow, correct?

11 A. That's correct. So the
12 abnormality of the neural section indicates the
13 other process, of loss of sensation, loss of pain
14 sensation.

15 Q. Do you know what a Renault body is?

16 A. Say that again.

17 Q. Do you know what a Renault body is?

18 R-E-N-A-U-T.

19 A. I think I've seen this term, but I
20 don't remember it.

21 Q. Okay. Does the S100 stain all
22 components of the nerve?

23 A. It only stains schwann cells.

24 Q. When you reached the opinion on
25 page 35 that that shows a degeneration of the

1 nerve, did you rule out the presence of nerve
2 structures other than schwann cells that might be
3 present?

4 A. There might be axons still there,
5 but that's not the point. The point is the nerve
6 is degenerating.

7 Q. And what's the clinical impact of
8 the degenerated nerve?

9 A. I just told you. There are
10 fibers, which are in the area, mainly not function.
11 It means that if they are sensory fibers, they may
12 not deliver signals. So that area which is
13 innervated through those fibers, will be numb. You
14 will not feel anything in that area.

15 Q. So it will not cause pain?

16 A. In the reverse, it will not feel
17 anything.

18 Q. But if it doesn't feel anything,
19 does that mean that it does not cause pain?

20 A. Including pain. It will not feel
21 touch, it will not feel temperature, it will not
22 feel pain.

23 Q. Okay. Anything else remarkable
24 about it then?

25 A. No.

1 Q. If you go to page 36, Figure Set 4.

2 A. Yes.

3 Q. You have, "A neural ganglia in
4 additional TVT cases."

5 Again, these are cases that you
6 previously worked up?

7 A. That is correct.

8 Q. What is a neural ganglia?

9 A. Neural ganglion is like a switch
10 box, or connection box for the autonomous
11 neuro system. The neuro system which is
12 innervating in the organs rather than skin and
13 mucosa.

14 Q. What is the significance of the
15 presence of this image of the neural ganglion?

16 A. It tells you that some of the
17 nerves, which we see in the specimens are
18 autonomous. So some of them go into the bladder.
19 That's one -- well, one important aspect of this.

20 The second important aspect is that the
21 ganglia themselves can be affected by the image.

22 So in first case, the nerves can be
23 affected, which are further away from the ganglia.
24 And second case scenario, the ganglia themselves.

25 Q. Is there anything about this image

1 on page 36 -- strike that.

2 This is one image, the second one
3 you've labeled, so it's just one image?

4 A. That is correct.

5 Q. Is there anything about the image
6 on page 36, that you can tell by light microscopy,
7 that there's anything abnormal about the ganglia
8 that's depicted there?

9 A. To begin with, as we saw the
10 nerves, the location was abnormal. So it's in the
11 scar tissue and it's inside the mesh.

12 Q. Is that the only thing about this
13 image and the ganglia that causes you concern?

14 A. No.

15 Q. What else?

16 A. I mean, that's about it. I don't
17 have any other concerns.

18 Q. Thank you. Page 37 you have:
19 "Innervation of mucosa overlying the mesh, H&E and
20 S100 of the same tissue area, four times.
21 Additional TVT cases."

22 Again, these are cases outside of the
23 consolidated group, correct?

24 A. That is correct.

25 Q. And are all these images just four

1 times?

2 A. The degree of magnification on the
3 top image is slightly lower, and magnification on
4 the lower is slightly higher. Again, this is
5 not -- it's hard to say exactly what's the degree
6 of magnification. Because they've been taken
7 through a camera and sort of objective, and then
8 cropped, and then resized to be reprinted so...

9 Q. What is the significance of the
10 image on the top where you showed mucosa, distorted
11 mucosa, and a measurement of 1 millimeter?

12 A. Significance is that the mesh is
13 right under the mucosa. So, if you touch the
14 mucosa, even if it's light pressure, it immediately
15 gets compressed into the mesh. It can be exposed,
16 I mean, the mucosa can breakdown.

17 Q. This is from the Edwards case,
18 isn't it?

19 A. It could be, I don't know. It's
20 old picture, it could be from the Edwards case.

21 Q. And this does not show an
22 exposure, correct?

23 A. It's not exposed, yes.

24 Q. It's not an erosion either yet?

25 A. In this specific image, it's not

1 exposed.

2 Q. Okay. And what's the significance
3 of the distorted mucosa?

4 A. Probably, it was getting close to
5 the exposure site. I don't remember specifics.

6 Q. Okay. But is it simply the fact
7 of the location of this mesh related to the mucosa
8 that you're pointing out here?

9 A. That is correct.

10 Q. Is that a surgical placement issue?

11 A. Not exactly. It can migrate, it
12 can move centimeters within the body.

13 Q. Or a surgeon can place it there,
14 correct?

15 A. Both.

16 Q. Yes. And you're not able to tell
17 from this image, whether the surgeon placed it
18 there or it moved there from somewhere else,
19 correct?

20 A. No. I know that all of them are
21 covered by mucosa after surgery. That's what
22 surgeons are trying to do.

23 Q. So again, I asked a bad question.

24 You can't tell from looking at the
25 image, whether the surgeon placed it there, or

1 whether it migrated there, correct?

2 A. That's correct.

3 Q. Thank you. And what's the
4 significance of the two images below that on
5 Figure Set 5?

6 A. It's the same image, the right
7 copy is labeled, the left one is not labeled. It
8 shows that the tissue in between mucosa and the
9 mesh is innervated.

10 Q. I see.

11 A. So if you compress mucosa, you are
12 hitting the receptors, hence small nerve branches
13 at the same time.

14 Q. Anything abnormal about the nerve
15 branches and twigs that you depict in those images?

16 A. Just the location.

17 Q. Okay. Page 38, "Additional TVT
18 cases." What does this show?

19 A. The same as it says on the
20 previous page, superficial location of the mesh,
21 overlying mucosa, innervation of the tissue and the
22 mucosa.

23 Q. And other than the presence of the
24 nerves in the mucosa, and the position of those
25 nerves relative to the mesh in the mucosa, is there

1 anything else remarkable about that image?

2 A. No.

3 Q. If we go to page 39, what is
4 vascular dilatation?

5 A. When the vessels are being
6 distended, so the outflow from the vessels is
7 obstructed for varying reasons. So there is more
8 fluid coming in, than fluid coming out.

9 Q. And what does mesh have to do with
10 vascular dilatation?

11 A. It caused it.

12 Q. How do you know that?

13 A. Because normally vessels are not
14 distended like this, there is a reason why the
15 outflow is obstructed.

16 Q. Are there any other causes for
17 vascular dilatation?

18 A. In normal tissue?

19 Q. Yes.

20 A. There are some other, like typical
21 example is hemorrhoids.

22 Q. I'm sorry?

23 A. Hemorrhoids.

24 Q. Hemorrhoids?

25 A. Hemorrhoids.

1 Q. I'm sorry. That's a southern West
2 Virginia way of saying it, I apologize.

3 A. Okay. So there is dilatation of
4 the vascular structure, blood stays in. If it's
5 lymphatic vessel, lymph will stay, so it will
6 distend and it becomes larger.

7 Q. Now, what is statis, S-T-A-T-I-S?

8 A. Stasis, sorry.

9 Q. Stasis. So stasis and tissue
10 edema; what does that mean?

11 A. Stasis means that the fluid is
12 stagnant in the vessels. So it accumulates there,
13 it doesn't outflow. And then after some time, this
14 fluid starts seeping into the tissue. So because
15 the blood vessels, or lymphatics are so backed up,
16 fluid starts going into the tissue; that's how
17 edema happens.

18 Q. Okay. The blue in the image is
19 polypropylene?

20 A. Yes.

21 Q. And that is moved in the image by
22 sample preparation?

23 A. That's correct.

24 Q. The artifacts?

25 A. Yes.

1 Q. And do you see any bark around the
2 polypropylene in those images?

3 A. Here.

4 Q. You pointed to the white. I'm
5 looking at the blue polypropylene itself. There's
6 no bark attached to any of the polypropylene, is
7 there?

8 A. Probably there is, but so low
9 magnification. I can see it clearly in this space.

10 Q. And you're referring now to the
11 upper right-hand corner and the black mark at the
12 lower right, correct?

13 A. Just above it -- no, no, here.

14 Q. Are you talking about --

15 A. The faint line. This faint line.
16 (Indicating).

17 Q. Oh, I see, okay.

18 And what's the clinical significance of
19 the vascular dilatation and statis tissue edema?

20 A. There's pressure inside. If fluid
21 accumulates to a degree, and then it starts
22 pressing in tissue, there will be pressure
23 accumulating.

24 Q. And to what extent can you
25 determine whether this pressure is present in an

1 area larger than what is presented in this one
2 slide?

3 A. What do you mean?

4 Q. Well, this obviously depicts these
5 findings within this slide. This slide is
6 4 microns thick, and I don't know how far across.

7 A. About two and a half, three
8 millimeters.

9 Q. Okay. Can you tell whether this
10 finding is present anywhere else in the woman from
11 which this was explanted?

12 A. Oh, it's patches. Somewhere it's
13 dilated, some areas are edematous, some are not.
14 Sometime the entire mesh is just sewed, or is shown
15 edema or dilatation. It depends, variables.

16 Q. And so you're unable to say,
17 looking at this figure on page 39, Figure Set 6a,
18 whether what you've described here was causing
19 symptoms in this woman, correct?

20 MR. ORENT: Objection.

21 THE WITNESS: Oh, I think we talked
22 about this before. Causing symptoms is a complex
23 process, and perceptions.

24 So this is abnormal mechanism, it is a
25 factor in pain mechanisms in some other areas.

1 Take hemorrhoids, you ask some patients, have them
2 painful; some patients have them not painful.

3 BY MR. THOMAS:

4 Q. I understand that. But it's also
5 fair to understand that this woman may have had
6 this issue in the histology, as you've described
7 it, but not be experiencing any symptoms because of
8 it, correct?

9 A. That's correct. The main thing is
10 it's an abnormal finding and it can cause pain.

11 Q. Okay. Do you know whether the
12 images that are on page 40 are --

13 A. Stasis.

14 Q. It's the same patient, 6a, 6b?

15 A. Could be, I'm not sure.

16 Q. You don't know, okay.

17 Again, the blue is polypropylene?

18 A. Yes.

19 Q. Are you able to tell in 6b, the
20 long, narrow white space in the lower left hand,
21 whether that is polypropylene that's present or not
22 present?

23 A. I'm not sure. The largest part is
24 difficult. I can see a little bit of the
25 degradation bark can be sitting on the non-degraded

1 bark and -- oh, I can see some of the mesh fibers
2 left here in this space.

3 Q. Okay. I'm looking at the area
4 above that one, though. This one (indicating).

5 A. Yes, it's folded and it trapped
6 some of the dye.

7 Q. Now how do you know that's folded
8 as opposed to just mesh, part of the interstitialcy
9 or part of the mesh being right adjacent to it?

10 A. Do you see this line, or this
11 slice, or cross-section of the fiber, it's folded
12 like this, and then there's a little bit of a dye
13 in this space, you can see it.

14 Q. So what you're showing here is
15 vascular dilatation stasis again?

16 A. Yes.

17 Q. Tissue edema?

18 A. Yes.

19 Q. Anything else remarkable about
20 this slide?

21 A. No.

22 Q. And the top is four times
23 magnification, and the bottom is ten times
24 magnification?

25 A. That's the best approximation.

1 Q. And my expert should have this
2 slide, correct?

3 A. Yes.

4 Q. Since you did 6a, 6b, 6c, does
5 that mean that it's from the same patient?

6 A. No. They group by the feature.

7 Q. Okay. So you don't look at it?

8 (Reporter sought clarification.)

9 A. Feature. So if it's the same
10 feature, it's the same figure number, but if it's
11 different images on different pages, they are
12 labeled A, B, C, D.

13 Q. What is the significance of the
14 edematous scar; the edema, loose scar?

15 A. It's edema, the same thing we
16 discussed before. The fluid stays in it, it builds
17 up pressure and can compress the structures.

18 Q. The same on page 41, 6c?

19 A. That's correct.

20 Q. Anything remarkable about the
21 image on page 41 beyond what you've described?

22 A. No.

23 MR. ORENT: Counsel, I'm wondering if
24 it's a good time to take a quick lunch break?

25 THE WITNESS: It feels like it.

1 MR. THOMAS: Sure, absolutely.

2 -- OFF THE RECORD DISCUSSION --

3 -- RECESS AT 1:01 --

4 -- UPON RESUMING AT 2:11 --

5 BY MR. THOMAS:

6 Q. Let's go to page 42 of your
7 report, please. I see you're open to it already.

8 A. Um-hum.

9 Q. Figure 7a says, "Involvement of
10 striated muscle by the mesh, H&E, 4 times.
11 Additional TVT cases."

12 Again, this is a case that is not
13 contained within the consolidated cases?

14 A. That is correct.

15 Q. Can you tell whether this is
16 TVT or TVT-O?

17 A. No.

18 Q. Does the fact that it's involved
19 striated muscle help you at all?

20 A. To a degree.

21 Q. Why would that influence which
22 kind of mesh it is?

23 A. It helps, because most frequently
24 if I see striated muscle, it's transobturator tape,
25 but occasionally I see striated muscle in

1 retropubic tapes as well.

2 Q. And what are you showing in Figure 7a?

3 A. I'm showing involvement of
4 striated muscle in the mesh.

5 Q. Tell me what you mean by that.

6 A. Striated muscle can be
7 incorporated right in the mesh, most likely mesh
8 migrated into the striated muscle. Or sometimes
9 it's just attached to it, so the fibrous capsule.

10 Q. On the left side is the actual
11 slide, and on the right side you've filled in with
12 a red, orange and a yellow, correct?

13 A. Yellow and red.

14 Q. Okay. The yellow is the
15 polypropylene?

16 A. That is correct.

17 Q. And the red is what?

18 A. Red is striated muscle.

19 Q. All right. And you said
20 "involvement of striated muscle by the mesh."

21 This shows striated muscle adjacent to,
22 but not incorporated in the mesh, correct?

23 A. Some parts of this incorporated,
24 sometimes it's just been fused, surface scar
25 tissue.

1 Q. Help me. Show me where it's
2 incorporated in it.

3 A. Well, in this case --

4 Q. You're referring to the lower
5 right?

6 A. In the lower panel, striated
7 muscle is encircling one of the mesh fibers.

8 Q. Okay. What's the distance, in
9 four times magnification from the muscle and the
10 mesh?

11 A. Within 1 to 2 hundred microns,
12 probably 100.

13 Q. Okay. And what's the significance
14 of that finding to your opinions in this case?

15 A. Well, if the mesh is fused with
16 the striated muscle, any contraction of the muscle
17 will tug on the mesh and prevent muscle from free
18 contraction.

19 Q. And what symptoms does that create?

20 A. The mesh is tugged, and you can
21 feel the mesh moving, pulling the nerves and other
22 tissues. So it's related to discomfort, feeling of
23 pressure and pain.

24 Q. Once again, is it true that you
25 can't say by looking at the images in 7a, that this

1 patient was experiencing pain or discomfort due to
2 the presence of the striated muscle next to the
3 polypropylene mesh?

4 A. I cannot say the degree of
5 sensation, but in this specific location, any
6 contraction of the muscle will tug on the mesh. So
7 there will be a degree of sensation, to what degree
8 I cannot say.

9 Q. All right. Anything else
10 remarkable about the images on 42?

11 A. No. Just striated muscle
12 involvement by the mesh.

13 Q. So let's go to Figure 7b on
14 page 43. You're using a different stain here, the
15 desmin stain.

16 A. That is correct.

17 Q. What is the significance of Figure
18 Set 7b on page 43 of your report?

19 A. Clearly, more visible in the
20 picture.

21 Q. What is more visible?

22 A. Striated muscle.

23 Q. And that's yellow in this image?

24 A. No, brown. Brown is striated
25 muscle.

1 Q. Brown, I'm sorry.

2 A. Because for a non-pathologist, it
3 would be hard to see where striated muscle is in
4 H&E section, but when we use desmin stain, it
5 demonstrates even the presence of striated muscle.

6 Q. I see. Are you able to tell me
7 whether the image in 7b is from the same patient as
8 the image in 7a?

9 A. No, likely not.

10 Q. Why do you say that?

11 A. Just my recollection.

12 Q. Are you able to tell me from what
13 patient 7b comes from?

14 A. I may or may not.

15 Q. How about 7a, do you know who that
16 came from?

17 A. Same thing, I may or may not.

18 Q. Okay. Tell me, please, the
19 significance of the image in 7b.

20 A. Now, we can see clearly that
21 muscle is on both sides of the mesh. So the mesh
22 is sandwiched between striated muscle, surrounded
23 by it.

24 Q. The same answers for 7b as 7a,
25 that when the striated muscles touch the mesh there

1 would be a tugging, discomfort and possible pain?

2 A. That is correct.

3 Q. But you don't know the extent to
4 which those may manifest themselves from this
5 figure?

6 A. The degree of sensation is
7 difficult to predict, it depends on multiple
8 factors.

9 I mean, it's clear that in this
10 location striated muscle contraction will be
11 restricted, and will cause movement of the mesh.
12 But the degree of sensation cannot be determined.

13 Q. What about page 44? Sorry, let's
14 go back to 43.

15 Did that cover the remarkable findings
16 in Figure 7b?

17 A. No, I mean --

18 Q. Is there anything else remarkable
19 about this?

20 A. We've covered everything.

21 Q. Thank you. Figure 8a, on page 44.

22 A. Yes.

23 Q. "Involvement of smooth muscle by
24 the mesh, H&E, 10 times. Consolidated cases."

25 Are you able to tell me whether this is

1 a TVT or TVT-O?

2 A. No.

3 Q. Okay. And you can't tell me which
4 patient it's from as you sit here?

5 A. I can determine for this specific
6 figures which patient it came from, because this
7 image has been numbered by this time.

8 Q. And can you tell right now, or do
9 you have to consult something?

10 A. No, no. I would have to go back
11 and check the names of the files.

12 Q. I see, okay.

13 And what's the purpose of depicting the
14 smooth muscle in this image?

15 A. To show that smooth muscle can
16 also be involved by the mesh.

17 Q. Is the smooth muscle impacted in
18 the same way as the striated muscle that you
19 described in the last two slides?

20 A. In a similar way, yes.

21 Q. Okay. Is the point here to show
22 that the smooth muscle is in close proximity to the
23 polypropylene mesh?

24 A. That's correct.

25 Q. And similar to 7a and 7b, any

1 contact with polypropylene with the smooth muscle
2 may cause some discomfort, tugging or possible
3 pain?

4 A. There is a little bit more to
5 smooth muscle. Because smooth muscle is present in
6 both vaginal wall and urethra and bladder.

7 So urethra and bladder have thicker
8 bundles of smooth muscle. Vaginal wall has wisps
9 of smooth muscle.

10 If mesh is in the vaginal wall, smooth
11 muscle, which is in the vaginal wall, can be either
12 attached to the scar plate. Or, if the mesh
13 migrates, it incorporates smooth muscle inside the
14 pores.

15 So if the smooth muscle of the vaginal
16 wall contracts, the mesh will interfere. So this
17 will be more of a sensation in the vagina, more
18 likely during intercourse, whether the vaginal wall
19 contracts.

20 Now, if we compare it with the smooth
21 muscle of the bladder and the urethra, it's a
22 different organ. So if mesh is interfering with
23 those bundles, they may not contract correctly. So
24 there may be interference with the function of
25 urethra and voiding, urination. And also,

1 sensation in the area.

2 Also, you should obstruct urethra
3 through compression of it. The mesh is pressing
4 against these thick bundles, and then compresses
5 the urethra. So it's indication that position of
6 the mesh was such that it was causing urinary
7 symptoms.

8 Q. Are you able to tell from Figure
9 8a, whether this tissue sample is from the vagina
10 or in the area underneath the urethra?

11 A. For Figure 8a, it would be
12 difficult because it's an H&E slide. If I stain it
13 with smooth muscle, then I can see exactly borders
14 and position of the muscle. Or, I can see it in
15 the microscope.

16 It's likely to be urethra, because the
17 area is more compact and there are bundles of it,
18 but I would have to look at the slide. But
19 comparing between these two applications, I would
20 favor the urethral muscle in this specific image.

21 Q. And it's fair to say that the
22 muscle here has not yet been incorporated into the
23 mesh, correct?

24 A. Not fully, but you can see that
25 the mesh is --

1 Q. Adjacent to?

2 A. Moving, or pressing against this
3 bundle. It's partially compressed; you see the
4 indentation made with the mesh here.

5 Q. Okay. And again, you don't know
6 the extent to which the situation, circumstances
7 described in this slide, may cause or contribute to
8 discomfort, tugging or pain?

9 A. If it's urethral muscle, it can
10 cause urinary outflow obstruction, because it's
11 clearly pressing on this part of the muscle. So
12 it's pressing on the whole urethra.

13 Q. But you don't know the extent to
14 which it was removed for obstruction, or why the
15 mesh was removed; do you?

16 MR. ORENT: Objection.

17 THE WITNESS: Yeah. Again the degree
18 of the symptoms would depend on many factors. I
19 can say that this picture shows that there was a
20 degree of compression of the muscle.

21 BY MR. THOMAS:

22 Q. Can you say from this slide, that
23 there was urinary dysfunction based upon this
24 slide?

25 A. Complete obstruction of the

1 urinary outflow, no, I cannot say that. I mean
2 there is interference, but the degree of it is more
3 complex question.

4 Q. Page 45, Figure Set 8b is the same
5 issue using a smooth muscle actin stain. And
6 because this is additional TVT cases, this is going
7 to be a different patient than 8a, correct?

8 A. That's correct.

9 Q. Is this a TVT or a TVT-O?

10 A. I cannot say.

11 Q. And is this the smooth muscle
12 stain that you referred to a few minutes ago?

13 A. That's correct.

14 Q. And what does the stain in Figure
15 Set 8b tell you?

16 A. So you can see clearly that the
17 smooth muscle is in wisps. So this is the smooth
18 muscle of vaginal wall, and it became incorporated
19 into the mesh.

20 So the mesh migrated in the tissue, and
21 this part of smooth muscle became incorporated in
22 the mesh pore.

23 Q. How can you tell from Figure 8b
24 that the mesh migrated or moved?

25 A. Because it contains normal structure.

1 Q. How does this figure -- how are
2 you able to tell from this figure that the mesh
3 wasn't placed there in the first place, as opposed
4 to migrated or moved there?

5 A. This space didn't exist before the
6 mesh was placed (indicating).

7 Q. Okay. And "this space" is what
8 you just drew as a circle?

9 A. Yes.

10 Q. And what does that space represent?

11 A. It's the space within the mesh.
12 So it was created in the body, when the mesh was
13 placed. When the mesh was placed, it's empty space
14 because tissue is disrupted. The mesh goes in, and
15 everything inside needs to be filled in with brand
16 new tissue. So this area was filled with tissue
17 after the mesh was placed.

18 But, we know that smooth muscle is a
19 more specialized type of tissue. It has very
20 limited ability for regeneration, so the scar which
21 can be produced. So if there is normal tissue
22 within the mesh pore, it means that it had been
23 incorporated later on, either through scar
24 contraction, which pulls normal tissue in, or
25 through mesh migration, which migrates into this

1 (indicating).

2 Q. What types of symptoms are present
3 from the findings that you have in Figure Set 8b?

4 A. I don't remember exact history for
5 this specific patient, but this position of smooth
6 muscle inside the mesh, is at risk for pain,
7 especially during intercourse, dyspareunia. Again,
8 the degree of these symptoms is difficult to
9 predict. But this is an abnormal position of
10 smooth muscle.

11 Q. Are you suggesting that every time
12 this patient would have sexual intercourse, that
13 she experienced pain due to this condition?

14 MR. ORENT: Objection.

15 THE WITNESS: How much of this will
16 contribute to her symptoms would be difficult to
17 predict. But as I said, this is an abnormal
18 position, and this abnormality provides a risk
19 factor for pain during intercourse.

20 BY MR. THOMAS:

21 Q. Okay.

22 A. Or just simply chronic pain.

23 Q. So as we've talked about before,
24 this is a risk factor in conjunction with other
25 things that may cause the conditions you're talking

1 about?

2 A. That's correct.

3 Q. Anything else remarkable about 45?

4 A. No.

5 Q. 46, Figure Set 8c.

6 Again, this is more smooth muscle with
7 smooth muscle actin stain, additional TVT cases.

8 Is this a third patient, do you know?

9 A. This is an older case.

10 Q. So is this a third patient within
11 this set?

12 A. Most likely.

13 Q. And it's an older case given the
14 camera that's used?

15 A. Yes.

16 Q. Can you tell whether it's a TVT or
17 TVT-O?

18 A. No.

19 Q. What is the significance of Figure 8c?

20 A. This is a nice picture, this is
21 urethral wall.

22 Q. You're talking about the muscle on
23 the right side of the image on the left?

24 A. Yup.

25 Q. Okay.

1 A. It's a thicker bundles of urethra,
2 and this part is vaginal wall. So this is part of
3 vaginal wall. And you can see the curve of the
4 sling was compressing urethra (indicating).

5 So this part of the sling was excised
6 with some of the urethral muscle.

7 Q. What is the significance of this
8 finding in this figure?

9 A. It shows the difference between
10 smooth muscle in the vaginal wall and smooth muscle
11 in the urethra, and the relationship of the mesh,
12 how it sits right on the muscle of the urethra.

13 Q. If you look at this, as it's going
14 to be in-situ, is it going to look like this?

15 A. Eventually it will look like this.

16 Q. So this is the urethral muscle,
17 and I'm holding Figure 8 sideways. So this shows
18 how the mesh has either the U-shape or the hammock
19 shape underneath the urethra; correct?

20 A. That is correct.

21 Q. Okay. So the positioning of this
22 mesh is really consistent with the way it should be
23 placed; is that correct?

24 A. It's the normal position. It's
25 not normal, intended position.

1 Q. Intended position, okay.

2 So what is significant about Figure 8c,
3 insofar as it relates to your opinions in this
4 case?

5 A. Well, I'm demonstrating that the
6 mesh is compressing right against urethra. And if
7 it was more pressure, it would start migrating into
8 urethra and sometimes I see that as well.

9 Q. When you say migrating, are you
10 talking about eroding into the urethra?

11 A. Yes.

12 Q. Okay. There's no evidence here,
13 though, of evidence of erosion into the urethra,
14 correct?

15 A. In this specific case, I don't
16 remember.

17 Q. Well, you don't see it in the
18 slide. You can't offer the opinion to a reasonable
19 degree of medical certainty that this mesh has
20 eroded into the urethra here, correct?

21 MR. ORENT: Objection.

22 THE WITNESS: Not in this image. And
23 the purpose of this different.

24 So you can see clearly, I should have
25 probably turned it. I should have turned it like

1 this (indicating). And this would demonstrate that
2 with more pressure, it would start migrating; in
3 this specific case, it didn't.

4 BY MR. THOMAS:

5 Q. Isn't this supposed to be right
6 underneath the urethra in order to control the
7 urine flow?

8 A. Yes, but I mean --

9 Q. Is this not placed properly?

10 MR. ORENT: Objection.

11 THE WITNESS: I wouldn't go and I
12 cannot testify exactly for placement.

13 To me, as a pathologist, I examine what
14 is abnormal and what can cause symptoms.

15 So if there are specific requirements
16 for placement or positioning, it would be a
17 clinical question.

18 BY MR. THOMAS:

19 Q. Okay.

20 A. So to me, this position, right
21 against smooth muscle of urethra, indicates that
22 sling is compressing against urethra directly.

23 So, with extra pressure, you can
24 collapse or compress urethra and cause urinary
25 outflow. And this is repeated in medical histories

1 that slings can cause urinary outflow and
2 obstruction.

3 And with more pressure, it will start
4 going through the muscle and become eroded. Also,
5 it will describe the clinical phenomena.

6 Q. And when you talk about disrupting
7 urinary outflow, is that the same thing as
8 retention?

9 A. Yes.

10 Q. And that's a recognized complication
11 from mesh placement?

12 A. Yes, it is.

13 Q. Anything else remarkable about
14 this slide?

15 MR. ORENT: Objection.

16 THE WITNESS: No.

17 BY MR. THOMAS:

18 Q. Is it fair to understand that
19 you're not able to diagnose urinary retention based
20 upon this single slide, correct?

21 A. Retention is a symptom, as we've
22 discussed before, symptoms are caused by multiple
23 factors together, so...

24 Q. Answer my question. Based on this
25 slide alone, you can't make that finding?

1 A. You can say that this position
2 creates a risk for obstruction.

3 Q. Yeah.

4 A. And a degree of compression of the
5 urethra.

6 Q. But like everything else, that's a
7 risk factor that you'd have to combine with other
8 things to determine whether, and to what extent
9 this could cause any problems in her, right?

10 MR. ORENT: Objection.

11 THE WITNESS: Not necessarily. It may
12 not need other factors. It may cause symptom on
13 its own. But the degree of the symptom is clinical
14 presentation.

15 BY MR. THOMAS:

16 Q. And you don't know what that
17 clinical presentation is as you sit here today?

18 A. That's correct.

19 Q. Page 47, Figure 8d. This is,
20 "Innervation within the mesh and between the mucosa
21 and the mesh. Also, images of muscle movement
22 involvement by the mesh." And this is a
23 publication?

24 A. That's correct.

25 Q. Do you know what kinds of mesh are

1 involved here?

2 A. I don't remember. I think two of
3 these images are from TVT or TVT-O. And two of
4 these images are from different mesh.

5 Q. Which ones are from TVT or TVT-O?

6 A. I don't remember now. I would
7 have to sort of do matching.

8 Q. Okay. What other manufacturers
9 did you look at?

10 A. AMS, Boston Scientific, Bard.

11 Q. And do you know which of those
12 manufacturers are depicted in this image?

13 A. No, I know for sure that there's
14 at least one TVT mesh here.

15 Q. At least one?

16 A. At least one. I don't remember --

17 Q. Do you know whether it was a TVT
18 or a TVT-O?

19 A. No.

20 Q. Okay. And what is the purpose of
21 this image?

22 A. It demonstrates same smooth muscle
23 involvement.

24 Q. Are you able to tell -- as I
25 understand the smooth muscle is either going to be

1 in the vagina or around the urethra, correct?

2 A. That's correct.

3 Q. Are you able to tell in Figure 8
4 whether this is the vagina or the urethra?

5 A. Let me see, because the pictures
6 are cropped to a degree.

7 Q. They're "cropped", did you say?

8 A. Cropped, yes. So I need the
9 larger pictures to -- let me see.

10 Maybe it's described in the caption.
11 (Witness reviews document.)

12 Just representative image. From what I
13 see, but it's not 100 percent, it may not be
14 100 percent correct.

15 C, would reflect urethral muscle. And
16 D would reflect vaginal muscle. But I'm not sure,
17 because most of the structures are cropped. It
18 just describes the fact that the mesh can
19 incorporate smooth muscle, from either origin.

20 Q. And just so we're clear. You're
21 pretty sure that one of these is a TVT or a TVT-O,
22 but you don't know which of the four figures in
23 Figure Set 8d is a Johnson & Johnson product?

24 MR. ORENT: Objection.

25 THE WITNESS: It would be either these

1 two or both (indicating).

2 BY MR. THOMAS:

3 Q. Okay. C and D, correct?

4 A. C and D. That is my recollection.

5 Q. What is it about those images that
6 cause you to believe it's an Ethicon TVT or TVT-O?

7 A. Oh, maybe not. Wait a second.

8 (Witness reviews document).

9 Sorry. I have to retry this. I don't
10 remember which exactly are TVT or TVT-O. It could
11 be one of these images in one of these.

12 Q. It could be any one of the four?

13 MR. ORENT: Objection.

14 THE WITNESS: Yes, I would have to go
15 back and check.

16 BY MR. THOMAS:

17 Q. Now this is smooth muscle; is that
18 what you're saying?

19 A. These are smooth muscle.

20 Q. In A, B, C and D?

21 A. No. Figure A shows neurovascular
22 bundle in the pore, we saw similar images before
23 that.

24 Figure B shows innervation between
25 sling and mucosa.

1 Figure C -- (witness reviews document.)

2 Q. Are you reading the text now?

3 A. Yes. So Figure C shows striated
4 muscle.

5 And Figure D, shows smooth muscle
6 unspecified, either from vagina or urethra.

7 Q. Okay. And is the purpose of this
8 image just to show the innervation of the mesh in
9 general?

10 A. Well, the purpose of the image is
11 to show all these pictures together. And I
12 included it because I knew that at least one
13 contains TVT or TVT-O, it is a supplementary
14 picture.

15 Q. Anything else significance for the
16 figures on page 47?

17 A. No.

18 Q. Page 48, Figure Set 9a. "Arterial
19 obliteration in the mesh scar plate, H&E 10 times.
20 Consolidated cases."

21 This obviously is from one of the
22 plaintiffs in the consolidated cases.

23 A. Yes.

24 Q. And you've indicated on the image
25 an obliterated artery. How can you -- what is it

1 about this image that tells you that this artery is
2 obliterated?

3 A. The lumen is collapsed.

4 Q. The lumen is collapsed?

5 A. Yes. The arterial wall is
6 degenerated, so clearly non-functional.

7 Q. And what does it mean to have an
8 obliterated artery?

9 A. It means that there is an area in
10 the body which had insufficient or disrupted blood
11 supply.

12 Q. Okay. When you say "insufficient
13 or disrupted", it can be disrupted without being
14 insufficient; can't it?

15 A. That's correct. There might be a
16 collateral circulation sufficient to supply.

17 Q. And you're not able to tell from
18 looking at this image in Figure Set 9a, that if
19 this is an obliterated artery, that it has any
20 clinical impact on the patient, correct?

21 MR. ORENT: Objection.

22 THE WITNESS: Again, could have had
23 only short-term impact, could have had longer term
24 impact. Short term would be necrosis, right after
25 the obliteration, or thrombosis, it's like heart

1 attack.

2 And then long-term would be scarring
3 and fibrosis. The same thing as a heart, people
4 who have insufficient cardiac output. If heart
5 muscle doesn't work as well as before the infarct,
6 so the same thing here, it would be a short term,
7 shortly symptoms or changes in the body. And then
8 longer term. Longer term would be caused more
9 fibrosis.

10 BY MR. THOMAS:

11 Q. And longer term there may or may
12 not be a problem, correct?

13 A. You mean how they would translate
14 into clinical symptoms?

15 Q. Yes.

16 A. The degree of translation into
17 clinical symptoms is more a complex process.

18 Q. Okay. Is there necrosis in this
19 image?

20 A. No. Because artery has supplied
21 the blood to somewhere else further down, so...

22 Q. Okay. So given your finding of an
23 obliterated artery, there are no clinical symptoms
24 manifested in this image, at this time that you can
25 point to, correct?

1 MR. ORENT: Objection.

2 THE WITNESS: Not in this area.

3 BY MR. THOMAS:

4 Q. Okay.

5 A. But it tells us that somewhere
6 else beyond this square picture, there was damage
7 for the tissue.

8 Q. There was or may be?

9 A. There was.

10 Q. Okay.

11 A. The degree of it is difficult to
12 determine. But there was.

13 Q. You'd have to see the tissue in
14 order to make that evaluation, correct?

15 MR. ORENT: Objection.

16 THE WITNESS: Yes.

17 BY MR. THOMAS:

18 Q. Where is the mesh in Figure 9a?

19 A. Somewhere beyond it.

20 Q. It's not in the slide?

21 A. Maybe right at the corners, I
22 don't know.

23 Q. But you didn't capture any mesh in
24 the slide on 9a?

25 A. I didn't crop it in.

1 Q. Let's go to page 49, Figure Set 9b.

2 A. Yes.

3 Q. It says, "Examples of capillary
4 thrombosis in the mesh scar plate."

5 What is "capillary thrombosis"?

6 A. When there are small thrombi
7 formed in the capillaries.

8 Q. What is the significance of
9 capillary thrombosis in the mesh scar plate?

10 A. The same as for arteries, just on
11 a small scale. So there's interruption of blood
12 supply in the smaller area. Artery can cover large
13 area, capillaries are covering small.

14 Q. Is there anything about what you
15 see in Figure Set 9b, that would tell you that this
16 patient is experiencing any clinical symptoms?

17 A. Again, the degree of manifestation
18 of this finding would be difficult to determine.

19 Q. It could be nothing?

20 A. May not be clinically apparent.

21 Q. And is this a single plaintiff or
22 is it two different plaintiffs? It says,
23 "additional TVT cases." I can't tell if it's one
24 patient or two.

25 A. I think it's from the same patient.

1 Q. Is it a TVT or TVT-O?

2 A. I think it was the Edwards case.
3 That's as far as I can recollect.

4 Q. Okay. Is there any mesh in Figure
5 Set 9b?

6 A. Right there (indicating).

7 Q. So that's on the lower left, okay.
8 Is there any mesh in the image above?

9 A. Not in the image. It was probably
10 right beside it.

11 Q. Okay. Let's go to Figure Set 10a
12 on page 50. It says, "TVT sling curled into a roll
13 cross-section through parallel walls. H&E stain
14 2.5 power magnification. Consolidated cases."

15 This shows a piece of curled mesh,
16 doesn't it?

17 A. That is correct.

18 Q. And this is the curled mesh that
19 you talked about before when you place it in
20 formalin that it will curl over on itself, correct?
21 When it's placed in formalin?

22 A. Did I say that it curls in
23 formalin? I said that mesh, which is curled in
24 scar tissue, curled in the body.

25 Q. I see. So you believe that this

1 curled in the body?

2 A. Yes.

3 Q. And on what basis do you believe
4 that?

5 A. Because that curl shape is
6 immobilized within the scar tissue, it's
7 incorporated in the scar tissue, in this shape.

8 Q. Okay. Anything other than the
9 curling phenomena that you've just described as the
10 purpose of Figure Set 10a?

11 A. Curling phenomena, scarring, it's
12 all encased in scar tissue.

13 Q. Okay.

14 A. That's about it.

15 Q. Okay. And at the top where we see
16 the blue, those are going to be artifacts?

17 A. No. The blue ones are
18 cross-sections of the blue filaments.

19 Q. I should have said, in places
20 where they don't fill the holes?

21 A. It can't be clear filament.
22 Because remember, half of the fibers in the sling
23 are blue, half of them are clear.

24 Q. Okay. Let's look at the top, off
25 of the slide there is a blue fragment. That

1 obviously has been pulled away from the slide,
2 correct?

3 A. That's correct.

4 Q. That's polypropylene?

5 A. That's correct.

6 Q. Let's go to set 10b. Is set 10b
7 from the same patient or a different patient?

8 A. I suspect it is the same patient.

9 Q. Do you know?

10 A. Not with 100 percent certainty.
11 But I think it is. It's just a different part the
12 of the same curled mesh.

13 Q. Okay. And does Figure Set
14 10b show anything new beyond what you've showed in
15 10a, or is it the same?

16 A. It's the same, just tighter roll.

17 Q. And if you look at the images at
18 the top, there's a blue line coming out of the top
19 right, and that's a polypropylene artifact?

20 A. Displaced polypropylene fibers.

21 You can also see dilated vascular channels.

22 (Reporter sought clarification.)

23 A. So in this area, there is vascular
24 dilation.

25 Q. Can you tell from these images,

1 10a and 10b, whether this mesh caused any symptoms
2 in the patient when it was implanted?

3 MR. ORENT: Objection.

4 THE WITNESS: My answer is the same.
5 Clinical symptoms is a multifactorial, complex
6 phenomena.

7 BY MR. THOMAS:

8 Q. This is a risk factor?

9 A. No, this is not a risk factor,
10 this is a mechanism, how the complications occur.

11 But then there is a patient in between
12 who feels the symptoms, and the body however reacts
13 and so forth. But in this case, the mesh is
14 rolled, so the pressure is distributed in a small
15 area.

16 The probability that it will compress
17 urethra is higher, because if it was flat, it would
18 have much larger distribution of pressure.

19 Q. So is the risks from this curl
20 mesh compression against the urethra and urinary
21 retention?

22 A. Yes, one of those.

23 Q. Do you know whether this patient
24 had urinary retention?

25 MR. ORENT: Objection.

1 THE WITNESS: I don't remember now.

2 Because my purpose for this report was to actually
3 show these things which can happen, and the
4 pathological changes which happen after mesh
5 placement.

6 And, symptoms which can factor in.

7 BY MR. THOMAS:

8 Q. Okay.

9 A. But I wasn't working on specific
10 connection between this pathological change, caused
11 that symptom in this specific patient.

12 Q. Okay. Anything else remarkable
13 about the images on 50 and 51?

14 A. No.

15 Q. Go to page 52. And you get
16 "Neurovascular bundle within curled mesh, four
17 times magnification. Consolidated cases."

18 Is this a different patient than was
19 depicted in 10a and 10b?

20 A. One of these, because I say that
21 it's curled mesh --

22 (Witness reviews document).

23 So likely it was one of these two.

24 Q. I think you told me -- well, maybe
25 I didn't hear this right. I thought you told me

1 that A and B were from the same person?

2 A. Most likely.

3 Q. Do you know?

4 A. I can tell you, but not right now.

5 I can just check the name of the files.

6 Q. And do you think that 10c, is the
7 same or different person?

8 A. Most likely it is the same person,
9 or one of the two. It could all be from one
10 patient, it could be from two patients.

11 Q. Okay. In the top part on 10c, on
12 page 52, you have a displaced piece of
13 polypropylene?

14 A. Yes.

15 Q. And what's the significance of
16 identifying this neurovascular bundle in the
17 figure?

18 A. As before, we were talking about
19 entrapment of the neurovascular bundle before. But
20 in this case, it's not just in pore. It goes in
21 the pore, and became entrapped in the curls.

22 So it's in between two layers of the
23 mesh right inside the curl. So it's secondary type
24 of compartment. Because before we're talking about
25 compartmentalizing nature of the mesh, and then we

1 talk about flat mesh, it's sort of third dimension.
2 So compartments are within the thickness of the
3 mesh. But when it curls, it creates secondary
4 compartment. Compartment which is encircled by the
5 mesh or between the folds.

6 Q. Anything that you can see in
7 Figure 10c, on page 52 that is abnormal or
8 symptomatic about that neurovascular bundle, other
9 than its presence in the scar tissue?

10 A. It's abnormal location.

11 Q. It's simply that, the abnormal
12 location?

13 A. Yes.

14 Q. Anything else?

15 A. The surroundings are abnormal.

16 Q. Okay. Anything else remarkable
17 about that image?

18 A. No.

19 Q. Let's go to page 53, section 10d.
20 This is, "A twisted TVT sling" from additional TVT
21 cases."

22 So this is one of your older cases,
23 correct?

24 A. Yeah. Earlier or concurrent.

25 Q. Is this a TVT or TVT-O?

1 A. I don't know.

2 Q. What is the significance of what
3 you've done in Figure 10d?

4 A. It shows that the mesh just
5 curled, and also twisted. To get the shape like
6 this out of flat tape, it has to curl and then one
7 end is twist.

8 Just think about it, how they put these
9 sections in this shape. So one end like this, and
10 the other one is probably like that (indicating).
11 Or maybe like this (indicating).

12 Q. Okay. Does that happen by
13 placement, or by migration in the body, or do you
14 know?

15 A. It's hard to figure out if you can
16 place it like this.

17 Q. Do you know?

18 A. I don't know. One thing I can
19 tell you, this shape was formed in the body and
20 then it became incorporated in scar tissue like
21 this.

22 Q. But you don't know whether that
23 happened on placement or in some other way?

24 A. No.

25 Q. Okay. Now, in Figure 2 and

1 Figure 3, you show different images of the yellow.
2 What's the purpose of doing gradations of the
3 yellow?

4 A. Well, this shows the planes of the
5 mesh. Just to help you to understand that we're
6 talking about the mesh which twisted.

7 Q. Okay. Figure 10e is explanted
8 mesh. This has been in formalin, correct?

9 A. Yes. I believe it was in
10 formalin.

11 Q. Okay. And no attempt to clean it
12 at all, correct?

13 A. That is correct.

14 Q. And the purpose here is to show
15 what you believe to be the curling of the mesh?

16 A. Well, it's not what I believe. I
17 observe curling. It's hard to show in the picture,
18 but when you look at it with just magnifying glass
19 or if you have good eyes, you can see that the mesh
20 is curled up and then it's all filled with scar
21 tissue.

22 Q. Is the purpose of this just to
23 show the simple curling, or are you trying to show
24 something beyond other than that?

25 A. No, just curling. And that the

1 curled shape is actually filled with scar tissue.
2 It's not formalin, as you'd like to say, causing
3 the curling. It was removed from the body in that
4 shape.

5 Q. Can you tell whether, assuming
6 this is curled in the body, whether it was curled
7 upon placement or curled after placement?

8 A. The only thing I can say, it can
9 happen, and it happened.

10 Q. Okay. But you don't know whether
11 it happened during placement or after placement?

12 MR. ORENT: Objection.

13 THE WITNESS: I don't know.

14 BY MR. THOMAS:

15 Q. If you go to page 55, Figures A
16 and B, set 10f. "A TVT sling with curled edges.
17 Right sling is TVT."

18 Are these two different slings or one;
19 do you know?

20 A. These are two different slings,
21 this is AMS, this one I remember.

22 Q. AMS is on the left?

23 A. Yes.

24 Q. And TVT is on the right?

25 A. Yes.

1 Q. Is it TVT or TVT-O?

2 A. I don't know.

3 Q. Does the AMS figure have any
4 relevance to your discussion in this case?

5 A. Not necessarily, no.

6 Q. Okay. Tell me what is significant
7 to you about the TVT in part B of set 10f?

8 A. See, the images which were taken
9 from publications were not cropped, so I don't
10 remove any panels. So in this image, I think I had
11 a TVT, I provided the entire --

12 Q. I understand, that's okay.

13 A. So in this case I can tell exactly
14 this is TVT, and this is a different manufacturer.

15 Q. All right. So what is the
16 significance of slide B?

17 A. It's curled, it's roped. You can
18 see it's not tightly -- it's not flat. It's
19 tightly curled.

20 Q. Can you tell whether it was placed
21 that way or whether that happened after placement?

22 MR. ORENT: Objection.

23 THE WITNESS: I can't say. The only
24 thing I can say is that it happened in the body.

25

1 BY MR. THOMAS:

2 Q. Okay. Anything else remarkable
3 about 10f on page 55?

4 A. No, just roping.

5 Q. Page 56, you have Figure Set
6 10f again. Is that a typo, or is that the same
7 mesh? It looks like a different mesh, it looks
8 like one of yours.

9 A. It's a typo.

10 Q. So this would be 10f --

11 A. No, it should be 10d.

12 Q. 10d?

13 A. I think it's the same specimen as
14 10e.

15 Q. Okay.

16 A. The same case, I believe. So this
17 case took two pieces. One piece was rolled like
18 this, like 10e.

19 Q. Okay.

20 A. And the second piece was flat
21 area. Sometimes one piece, especially if it's
22 heat-treated doesn't curl. So there is a segment
23 of mesh --

24 Q. What do you mean heat-treated,
25 during removal?

1 A. No, during manufacturing.

2 Q. Are you talking about heat-treated
3 as in laser cut?

4 A. No, the entire surface is
5 heat-treated, not just edges.

6 Q. And so what impact -- I didn't see
7 it anywhere in your report, that heat somehow in
8 the manufacturing process will impact the ability
9 of the mesh to lay flat in the body?

10 A. It doesn't curl -- oh, doesn't
11 curl as much.

12 Q. Okay.

13 A. It's more stable structure because
14 fibers are welded together, or to a degree
15 connected together.

16 Q. Okay.

17 A. I know that some of the tapes --

18 Q. Some other manufacturers?

19 A. Other manufacturers, middle
20 portion is heat-treated.

21 Q. Okay. So did Boston Scientific
22 mention it?

23 A. I don' know.

24 Q. It's all right.

25 A. I don't remember now. I mean some

1 of them were coming out first, with no heat
2 treatment, and then later on they became
3 heat-treated.

4 So some portions don't curl because of
5 heat treatment, or just don't curl because of other
6 factors. So in this specific case, there was a
7 segment of the sling removed, and it was curled.
8 And in another segment of the sling removed and it
9 remained flat in the body.

10 Q. Okay. Do you know why?

11 A. No, I don't know. One of the
12 reasons can be heat treatment.

13 Q. It could also be placement?

14 A. It could also be placement or
15 location.

16 Q. And what is the purpose of the red
17 and the yellow on the image on 10f on page 56?

18 A. It just demonstrates how flat
19 section of the mesh looks, and how a curled section
20 of the mesh looks. Because here, cross-section,
21 this mesh.

22 Q. Yes?

23 A. And then it came on histological
24 sections like this.

25 Q. Is this from a case, additional

1 TVT cases?

2 A. Yes.

3 Q. Has this been produced in a report
4 somewhere? I've never seen this image in a case
5 anywhere, I'm just curious to know if it's been
6 published in a report someplace.

7 A. I don't want to disclose that if
8 it has not been produced, so it have been produced.

9 Q. Let me ask you this. Here is why
10 I ask: Generally, as you know, at least with
11 Ethicon, we divide these meshes before any work is
12 done on them.

13 Did you divide this mesh with Ethicon
14 before you did this work on 10f?

15 A. It could be that was divided with
16 your expert, so we were taking pictures together.

17 Q. Okay. Well maybe that's right.

18 A. I think it was the case. Now I
19 can vaguely remember the issue because we were
20 discussing how we're going to cut this diagonal or
21 cut it --

22 Q. I see.

23 A. And so I remember him standing
24 beside me, and I was taking those pictures.

25 Q. I see.

1 A. I took this picture, then this
2 picture, then we probably have similar pictures
3 from him.

4 Q. And I apologize, I've been asking
5 this question a lot, and I don't know if I've asked
6 you about this slide, so if I have, I apologize.

7 You don't know whether the curling
8 depicted in 10f, on page 56 occurred during
9 placement or after placement, do you?

10 A. No, I don't.

11 MR. ORENT: Objection.

12 BY MR. THOMAS:

13 Q. Page 57, Figure Set 10g. "A TVT
14 sling with curled edges." Is this a different TVT
15 than the ones we've looked at?

16 A. I think these are the pictures of
17 the same case. Again, that is my recollection, I'm
18 not 100 percent sure, but I think.

19 Q. Do you know if this is a TVT or a
20 TVT-O?

21 A. No.

22 Q. Are you trying to show anything by
23 these images on 10g other than a different
24 depiction of what's in 10f?

25 A. Well, no. This just shows the

1 curling state, this cross-section (indicating).

2 Q. Okay. So it's your best
3 recollection that the images in 10e, 10f and 10g,
4 are from the same mesh, same patient?

5 A. Yes, likely than not, these are
6 all from the same patient.

7 Q. But you're not sure?

8 A. No. As I said, the purpose of
9 this report was to analyze the device as a whole,
10 not the individual patients.

11 Q. 10h: "TVT sling with curled
12 edges. Additional TVT cases"?

13 A. Yes.

14 Q. Do you know where -- is this a new
15 patient; do you know?

16 A. It's older pictures, taken by old
17 camera.

18 Q. Do you know whether this is a
19 TVT or TVT-O?

20 A. No.

21 Q. What is the purpose of this image?

22 A. It show the cross-section of the
23 curl. And you can see it clearly, the whole field
24 is scar tissue. This indicates that this curl
25 shape was formed in the body and then the scar

1 tissue growing inside and filled the two-block
2 structure.

3 Q. And are you able to tell from this
4 image, whether it was curled on placement or curled
5 after placement?

6 MR. ORENT: Objection.

7 THE WITNESS: No.

8 BY MR. THOMAS:

9 Q. Anything else remarkable about
10 Figure Set 10h?

11 A. No. Curling, scar encapsulation,
12 scar filling.

13 Q. Page 59, Figure Set 10i:
14 "Neurovascular bundle with rolled TVT tape, S100
15 stain. Additional TVT cases."

16 Is this from the same or a different
17 patient as set 10h?

18 A. I don't remember now.

19 Q. Do you know if it's a TVT or
20 TVT-O?

21 A. No.

22 Q. What are you trying to show in
23 Figure 10h?

24 A. It's a single picture for single
25 purpose as 10c, on page 52. A neurovascular bundle

1 is inside the roll of the curled tape.

2 Q. And is there anything about the
3 depiction in the neurovascular bundle in set 10i on
4 page 59 that is irregular or abnormal other than
5 its presence in the scar plate?

6 A. Well, it's bent by the mesh fiber,
7 you can see clearly that it deviates from straight
8 course.

9 Q. Anything about that that makes you
10 have an opinion that this is causing any symptoms
11 in the person who has this mesh?

12 MR. ORENT: Objection. Form.

13 THE WITNESS: Probably, the nerve is
14 irritated by these fibers higher, because it is a
15 direct compression on the nerve.

16 BY MR. THOMAS:

17 Q. But there's nothing about this
18 slide, just like the other slides, which tells you
19 that the neurovascular bundle in Figure Set 10i,
20 actually caused symptoms in the person who had this
21 mesh?

22 MR. ORENT: Objection.

23 THE WITNESS: We discuss this before.
24 The degree of symptoms, the expression by the
25 patient is a complex process.

1 So I can say that this is abnormal,
2 this is a mechanism for symptoms, and then that can
3 happen.

4 BY MR. THOMAS:

5 Q. And the reason why you say it's
6 abnormal is because the mesh fiber causes this
7 bundle to alter its path?

8 A. Yes.

9 Q. Anything else?

10 A. No.

11 Q. Page 60.

12 A. Yes.

13 Q. Figure Set 10j: "A rolled TVT
14 sling sectioned parallel and perpendicular to the
15 roll. Additional TVT cases."

16 Do you know whether this is a TVT or
17 TVT-O?

18 MR. ORENT: Objection.

19 THE WITNESS: No.

20 BY MR. THOMAS:

21 Q. What is the significance of this
22 slide to show what you showed in previous slides.
23 That is, the fact of the curling?

24 A. Fact of the curling and mechanism
25 for erosion on page 61, I demonstrate how the

1 erosion occurred. Because one end of this curled
2 tape became eroded.

3 Q. Okay. So this is, the dark end of
4 the tape on page 60 and on 61, it is in fact an
5 erosion?

6 A. Yes, it's --

7 Q. Where did it erode?

8 A. In the mucosa, in vaginal mucosa.

9 Q. Did it erode into another organ?

10 A. No, it eroded through the mucosa
11 into the vagina.

12 Q. Do you distinguish between an
13 erosion and an exposure?

14 A. Technically, there is a
15 distinction. The terms are used interchangeably,
16 so there is no agreement which one is --

17 Q. Let's use the technical terms,
18 just so you and are communicating. Is this an
19 erosion or an exposure?

20 A. Both.

21 Q. Okay.

22 A. Because the mucosa eroded on top
23 of it and mesh became exposed.

24 Q. Okay. But in terms of the mesh
25 going into or eroding into another organ, that

1 didn't happen here?

2 A. Well, it eroded into the mucosa.

3 Q. Okay. But just the mucosa, not
4 the bladder, not the rectum?

5 A. Not the organs. Because it is a
6 different location.

7 Q. All right. And do you remember
8 this patient?

9 A. No.

10 Q. Do you know how this patient was
11 treated?

12 A. By sling excision.

13 Q. Do you know how it worked out?
14 How she recovered from the excision?

15 A. Better that she didn't have eroded
16 mesh anymore after surgery. Maybe it eroded again
17 in a different place.

18 Q. Do you know whether she
19 experienced pain as a part of this?

20 A. Most likely she did.

21 Q. Do you know whether she
22 experienced pain as part of this?

23 A. The degree of pain, as I said, I
24 don't remember now. But most likely she did.

25 Q. You have not consulted her records

1 to see the extent to which this was a painful
2 experience for her?

3 A. This is commonsense. This is a
4 chronic and open wound; would it hurt? Of course
5 it would.

6 Q. Go to page 61. Figure Set 11b.
7 Is this the same mesh?

8 A. No, it's a different one.

9 Q. All right. Is this a TVT or a
10 TVT-O?

11 A. I don't know.

12 Q. And what are you trying to show in
13 Figure Set 11b?

14 A. Similar mechanism for erosion, the
15 mesh somehow rotated, probably through curling of
16 the edges and then became exposed. The edge
17 pierced through the mucosa.

18 Q. And this is an erosion, as you've
19 defined it, in the last section, some people may
20 call it an exposure, correct?

21 A. Yes. It's called -- if you want
22 to call exposure, we will call it exposure. So the
23 mesh became exposed.

24 Q. And what does the mesh in this
25 tissue sample tell you?

1 A. The position, see the position is
2 towards the mucosa. So it's not bilateral to the
3 mucosa, it's angled. And the edge, or the end of
4 the tape became exposed, pierced through the
5 mucosa. And the site of exposure became infected
6 and now there is acute inflammation surrounding.

7 Q. How do you know that this mesh was
8 infected?

9 A. Because there is acute
10 inflammation in there.

11 Q. Do you know how long this woman
12 had this sling before it was removed?

13 A. I don't remember.

14 Q. Are you able to tell from this
15 slide whether this mesh was placed this way or
16 whether it changed after it was placed?

17 A. It's hard to place it like this,
18 because you can see it's clearly perpendicular. So
19 I just cannot imagine it.

20 Q. Do you know?

21 MR. ORENT: Objection.

22 THE WITNESS: I don't know for sure,
23 but this would be a really difficult position to
24 achieve during placement.

25

1 BY MR. THOMAS:

2 Q. Anything else remarkable about
3 your description of set 11b?

4 A. No, we discussed most of it.

5 Q. Anything else you want to talk
6 about? You said "most".

7 A. Sorry.

8 Q. Page 63, Figure Set 11c: "Exposed
9 edge of TVT sling rotated towards the mucosa.
10 Additional TVT cases".

11 Do you know whether this is a TVT or
12 TVT-O?

13 A. No, I don't.

14 Q. And what is your purpose of
15 including Figure Set 11c?

16 A. Just mechanism of exposure,
17 because the edge is pointing towards mucosa.

18 So it's a near exposed position in this
19 case. Probably exposure occurred somewhere either
20 more superficial, or deeper in the block.

21 Q. As you're looking at that mesh, is
22 the mesh -- you show the yellow portion of the mesh
23 going from the bottom of the figure to the top of
24 the figure. Is that the width of the mesh?

25 A. With the length, it's very hard to

1 determine in this place. So the mesh is either in
2 this shape (indicating), or this shape
3 (indicating).

4 In any case, one of the edges is
5 pointing towards mucosa.

6 Q. When you talk about -- strike
7 that. This mesh when placed, is going to stretch
8 from one side of the abdomen to the other, isn't
9 it?

10 A. Yes. But we are talking about
11 mucosa. So it is a very short stretch of the mesh
12 right where it goes between the urethra and vaginal
13 wall.

14 Q. I understand that. But my point
15 is, the only thing that can be exposed there is the
16 midpoint, not the ends, correct?

17 A. Unless you cut one end, and then
18 it becomes exposed again.

19 Q. Okay. And in order to cut the
20 end, you'd have to cut the end at the vaginal
21 mucosa, correct?

22 A. Inside. So what happens -- first
23 exposure occurs, it curls up like this. So this
24 part is exposed, there is a revision surgery, one
25 end is cut, the patient is left and sometimes it

1 curls up like this.

2 Q. Is this a multiple revision?

3 A. I don't know.

4 Q. You don't know?

5 A. (Witness nods.)

6 Q. Okay. For the other mesh
7 erosions, or exposures that you've discussed on 58,
8 59, 60, 61, 62 and now 63, do you know whether
9 those are first revision cases, second revision
10 cases, or multiple revision cases?

11 MR. ORENT: Objection.

12 THE WITNESS: I don't remember exactly.
13 Sometimes it's first revision, sometimes five, six
14 revisions.

15 BY MR. THOMAS:

16 Q. You just don't know?

17 MR. ORENT: Objection.

18 THE WITNESS: If I go through records,
19 if it was individual report of a case, I go through
20 records thoroughly, so I know exactly how many
21 revisions it was.

22 BY MR. THOMAS:

23 Q. Go to page 64. Figure Set 11b, is
24 that part of Figure Set 11c, or is that different?

25 A. No, it's different.

1 Q. How can you tell?

2 A. It's a different slide.

3 Q. Okay. Is it a different patient?

4 A. I don't remember.

5 Q. Okay.

6 A. It may or may not be.

7 Q. Okay. Do you know if it's TVT or

8 TVT-O?

9 A. No.

10 Q. Page 65, Figure Set 11e; isn't
11 that the same as Figure Set 11c?

12 A. I just noticed, something
13 happened.

14 Q. You liked that one?

15 A. Could have been pasted twice or
16 selected and pasted -- I don't remember. Something
17 happened here. So I probably intended to insert
18 different picture, but this one made it.

19 Q. Okay. I think we can say that
20 63 and 65 came from the same patient?

21 A. Yes. It just shows you that I
22 don't have an army of people helping me, I'm just
23 alone.

24 Q. I understand. Let's go to
25 page 66, Figure Set 12.

1 A. Yes.

2 Q. This is additional TVT cases. Do
3 you know whether this is a single mesh or multiple
4 meshes?

5 A. What do you mean a single mesh --

6 Q. There are four frames here.

7 Excuse me, there are two frames here.

8 Do you know if it's the same one
9 patient or two?

10 A. No.

11 Q. You don't know whether it's one or
12 two?

13 A. No.

14 Q. Do you know whether it's TVT or
15 TVT-O?

16 A. No.

17 Q. What are you trying to show in the
18 top image on page 66, Figure Set 12.

19 A. Acute inflammation at the site of
20 exposure.

21 Q. When you say acute inflammation,
22 is that different from infection?

23 A. No. Acute inflammation is
24 reaction to infection. Technically, it's the same
25 pathological process.

1 Q. I was just going to ask you that.

2 Can you diagnose infection from this slide?

3 A. Yes, I can.

4 Q. And based on what?

5 A. Based on the acute inflammation.

6 Q. Okay. And what is it about the
7 slide that shows the acute inflammation?

8 A. The neutrophils.

9 Q. And the slide below that, again,
10 shows acute inflammation, and that may or may not
11 be the same patient?

12 A. That's correct. I have feeling
13 that they are different patients. I think one
14 of -- the top one is the later case, the bottom one
15 is an earlier case.

16 Q. As you sit here, do you know which
17 ones they are?

18 A. The quality of the histology and
19 the quality of the picture.

20 Q. In the top image, where you show
21 the acute inflammation, is there mesh in that
22 image?

23 A. Underneath, if you go a little bit
24 over.

25 Q. This doesn't appear in the image,

1 correct?

2 A. You're correct.

3 Q. Thank you. And in the lower image
4 on Figure Set 12, the yellow represents
5 polypropylene?

6 A. That is correct.

7 Q. And the presence of neutrophils
8 again shows the acute inflammation?

9 A. That's correct.

10 Q. Anything else remarkable about
11 that slide?

12 A. No.

13 MR. THOMAS: I need to take a break,
14 please.

15 -- RECESS AT 3:19 --

16 -- UPON RESUMING AT 3:23 --

17 BY MR. THOMAS:

18 Q. Doctor, I understand from prior
19 depositions that when you analyzed your
20 medical-legal cases that you prepared your own, for
21 lack of a better description, your own pathology
22 report. I think you called it a synoptic recording
23 for each of the plaintiffs?

24 A. Not for medical-legal. I do it
25 for all mesh cases, it's a part of research.

1 Q. Do you have those kinds of
2 recordings for all of the patients that are in your
3 report?

4 MR. ORENT: Objection.

5 THE WITNESS: May or may not. Probably
6 I don't have for all patients. Some cases are
7 probably not even signed out, so the report is not
8 completed yet.

9 BY MR. THOMAS:

10 Q. I guess my point is that we didn't
11 get any of those on your thumb drive. And I'm
12 curious if there's some of those that we don't
13 have. We have a lot of them in the Huskey, Edwards
14 case or the Bellew case -- in the Bellew case, you
15 produced those to us for the --

16 A. Yes. When I started doing my
17 research, I realized that I needed more or less
18 standardized approach when I examined the meshes.

19 And I started entering them as a
20 synoptic report, which is a specific pre-set number
21 of parameters, so I don't forget and they're all
22 analyzed in the same manner so they can compare
23 them. It has nothing to do with medical-legal
24 cases, or nothing else. It's pure documentation
25 for research purposes.

1 Q. Do you have that for each of the
2 slides that are in this report?

3 A. As I said --

4 MR. ORENT: Objection.

5 THE WITNESS: -- I don't have all of
6 these patients, some of the reports are not
7 finalized.

8 BY MR. THOMAS:

9 Q. I'm going to ask you to produce
10 those that you do have.

11 I have a --

12 A. If it's medical-legal case and
13 you're entitled to see the information.

14 Q. Okay. I have a title of a study,
15 we talked before about your chemical oxidation
16 study you were performing, and I asked you about
17 the recipe for the chemicals to which you're
18 exposing the TVTs to.

19 A. You mean hydrogen peroxide with
20 chromium salt catalyst?

21 Q. Yes.

22 A. Okay. I remember.

23 Q. And there was a study we found
24 called, "Controlled Peroxide Degradation of
25 Polypropylene - Rheological Properties and

1 Prediction of MWD From Rheological Data". Lead
2 author, Azizi, A-Z-I-Z-I. Including I. Ghasemi,
3 G-H-A-S-E-M-I, and M. KARRABI, K-A-R-R-A-B-I; does
4 that ring a bell?

5 MR. ORENT: Objection.

6 THE WITNESS: You're asking the wrong
7 person, I'm really bad with names. I'm a
8 pathologist, I remember the slides but I don't
9 remember the names.

10 BY MR. THOMAS:

11 Q. Do you have the study that you
12 used to come up with the recipe?

13 A. Yes, I do. I can find it in my
14 hard drive, and I can find it.

15 Q. Okay. Good.

16 A. It's most likely at least in the
17 reference materials as well.

18 Q. In the reference materials to your
19 report?

20 A. Yes.

21 Q. Okay. How did you determine which
22 of the slides from your total number of TVT-O and
23 TVT cases to include in the report?

24 A. I went to features. So every time
25 I would be describing a specific feature in the

1 opinions, I would go back in my pool of images, for
2 TVT and TVT-O cases, and search for best images
3 representing that specific feature.

4 Q. I see. So when you say "best
5 images", you went back through about 100 different
6 TVTs and TVT-Os did you say?

7 A. No, I said slings.

8 Q. I'm sorry. How many TVTs and
9 TVT-Os have you looked at?

10 A. Ballpark of 30 to 40.

11 Q. Okay. And so you went back
12 through your 30 to 40 to identify those that best
13 represented the features that you wanted to show?

14 A. Images.

15 MR. ORENT: Objection.

16 BY MR. THOMAS:

17 Q. Okay. Images?

18 A. I didn't take new images of
19 various cases, I just used those images which were
20 taken already. The only new images that I produced
21 are the cases I received as a consulting trial set.

22 (Reporter sought clarification.)

23 A. Trial set, as a set to facilitate
24 at trial.

25 Q. Let's go to Exhibit No. 2.

1 Exhibit No. 2 is your supplemental
2 report served two days ago.

3 A. Yes.

4 Q. And when you received this, you
5 received slides from CAMC?

6 A. Yes.

7 Q. You didn't create your own slides?

8 A. No, I did the staining.

9 (Reporter sought clarification.)

10 A. My lab did staining.

11 Q. Do you know whether this is a TVT
12 or a TVT-O?

13 A. No, I don't remember now.

14 Q. Okay.

15 A. I didn't review any medical
16 records for the consolidated trial cases.

17 Q. And if you look at -- your pages
18 aren't numbered, but the first image, which is
19 identified as supplemental Figure EM1, it says:
20 "Portion of excised mucosa with underlying mesh,
21 H&E magnification equivalent to 1.6X objective".

22 What is the significance of this image?

23 A. It's just from my review showing
24 where the mesh is and how it relates to the mucosa.

25 Q. Is there anything significant

1 about this image in terms of risk factors or issues
2 related to symptoms, clinical symptoms?

3 A. Well, it's close. So it's an
4 overview of the part which didn't get exposed but
5 it shows the proximity. You know, that's
6 significant.

7 Q. And again, you don't know whether
8 that was placed there or if it migrated there after
9 placement, correct?

10 MR. ORENT: Objection.

11 THE WITNESS: That's correct.

12 BY MR. THOMAS:

13 Q. Okay. Anything else remarkable
14 about supplemental Figure EM1?

15 A. No, there's scar tissue which
16 encapsulates and fills the pore; that's about it.

17 Q. Okay. Supplemental Figure EM2.
18 Is this part of the same slide or is this a
19 different slide?

20 A. Oh, it's the same block.

21 Q. Got it.

22 A. Yeah, I think it's the same slide
23 because I had only one H&E slide.

24 Q. It says in the first page you
25 received unstained histological slides, plural.

1 Did you only have one?

2 A. For H&E, I stain only one slide.

3 So one slide was stained by H&E method, one slide
4 smooth muscle actin, and one slide S100 protein.

5 Q. Okay. So supplemental Figure EM2
6 is just more of a magnification of Figure EM1,
7 correct?

8 A. Yes, I think you can match it,
9 it's from here.

10 Q. And again, what you're trying to
11 show is the foreign body reaction and inflammation?

12 A. That is correct.

13 Q. Where is the bark in this image?

14 A. Which image? The EM2?

15 Q. Yes.

16 A. Maybe out of focus, maybe not
17 there.

18 Q. Okay. If you go to supplemental
19 Figure EM3, this is another portion of the same
20 image, correct?

21 A. I think it's a different fragment,
22 from the same slide but from a different piece of
23 tissue. There were several pieces of tissue on the
24 slide.

25 Q. I see. And what is the purpose of

1 showing supplemental Figure EM3?

2 A. Again, shows mucosa and proximity
3 of the mesh to mucosa. There is less than a half
4 millimeter between the mesh and mucosa.

5 Q. What is the distance between those
6 two mesh fibers that are shown there?

7 A. About a millimeter.

8 Q. Okay. Supplemental Figure EM4,
9 again, you're showing the foreign body inflammatory
10 reaction?

11 A. That's correct.

12 Q. If you go to supplemental Figure
13 EM5?

14 A. Yes.

15 Q. You indicate in the description,
16 "acute inflammation and indication of mesh erosion
17 and bacterial infection".

18 Do you know whether this patient was
19 diagnosed with an infection?

20 A. No, I didn't read the records. I
21 can see clearly there is bacterial infection
22 triggering acute inflammation. If they saw it
23 clinically or they didn't, I don't know. But even
24 if they didn't, I would tell them there was an
25 infection.

1 Q. Okay. Are you able to tell from
2 these images that there was in fact a mesh erosion
3 or mesh exposure?

4 A. Yes.

5 Q. And how can you tell that?

6 A. There was a breakdown of mucosa
7 and entry for infection. That's why I can see
8 acute inflammation.

9 Q. Where is the breakdown of the
10 mucosa?

11 A. I don't know. It didn't get in
12 the section.

13 Q. Are you assuming there's a
14 breakdown of mucosa? You don't show one on the
15 slide, correct?

16 A. It's not an assumption. I can
17 tell you with 100 percent certainty that there was
18 a breakdown in the mucosa. Because if mucosa is
19 not broken down, there is no bacterial insemination
20 and acute inflammation.

21 Q. Supplemental Figure EM6, you
22 identify an obliterated artery?

23 A. That is correct.

24 Q. Anything remarkable about that
25 finding beyond what we've talked about before, the

1 other obliterated artery?

2 A. No. Exactly the same finding;
3 interrupted blood supply.

4 Q. Which may or may not have clinical
5 significance?

6 MR. ORENT: Objection.

7 THE WITNESS: The degree of the changes
8 may or may not be clinically apparent.

9 BY MR. THOMAS:

10 Q. Okay. Because if the blood flow
11 is reduced or interrupted, they may receive blood
12 flow from other sources that would vascularize this
13 area?

14 A. Yes. And then that was fibrosis,
15 and then you mix up fibrosis which is caused by the
16 mesh, then fibrosis lead to ischemia.

17 It's a complex setting; how much of
18 that would translate from one specific symptom
19 would be difficult to discern.

20 Q. Obliteration of arteries is a risk
21 in any surgery of the pelvic floor, isn't it?

22 MR. ORENT: Objection.

23 THE WITNESS: Yes, there would be a
24 risk for obliterated artery. But when you say
25 obliterated artery in the tissue, which is not

1 changed otherwise, because to obliterate an artery
2 during surgery, you have to transect it.

3 So by the time of mesh placement, this
4 part would be separated. So this is an intact
5 structure, which was not transected during surgery.
6 It became obliterated later on.

7 BY MR. THOMAS:

8 Q. If you go to supplemental -- how
9 can you tell that it happened after placement?

10 A. It's not transected during
11 surgery.

12 Q. I see.

13 A. See how are the arteries being
14 damaged --

15 Q. I understand.

16 A. -- they get transected.

17 Q. I understand. Supplemental Figure
18 EM7a, "innervation of the scar tissue encapsulating
19 the mesh, S100". What are you showing in EM7a?

20 A. Nerve branch. EM7a and 7b is the
21 same image; 7b is labeled copy of 7a.

22 Q. Okay. And the arrows are pointing
23 to what?

24 A. Nerve branches, or nerves.

25 Q. And for the nerve and nerve branch

1 on the upper right-hand corner, how far is that
2 from the mesh?

3 A. This one is --

4 Q. I'm talking about this one, upper
5 right?

6 A. Oh, this one. See, with this one
7 I don't even know. Maybe there is fiber right
8 there, so it's pinching it.

9 Q. Do you know whether that's fiber
10 or not?

11 A. That is hard to determine, I
12 suspect there is, but I wasn't sure therefore I
13 didn't put it.

14 Now, looking at this image, I think
15 there was a fiber. So that curvilinear shape is
16 actually fiber compressing.

17 Q. How do you know that without
18 looking at it?

19 A. Well, there's density, increased
20 density. Similar to this area, the collagen is
21 compacted right around the fibers.

22 Q. The tissue itself is pretty
23 irregular, isn't it?

24 A. Well, see, this is clearly not the
25 place where mesh fiber was. Because there is no

1 capsule. If you look here, there is a capsule
2 around the fiber, and if you look there, there is a
3 capsule around the fiber. So I suspect there was a
4 fiber here.

5 Q. Okay.

6 A. Not here, but there.

7 Q. Looking at those nerves, is there
8 anything about the appearance of those nerves on
9 light microscopy that suggests to you they were
10 causing pain to the patient while the mesh was in
11 place?

12 A. Could you repeat the question.
13 I'm getting tired, sorry.

14 MR. THOMAS: Would you repeat it for
15 me, please?

16 -- REPORTER'S NOTE: Question read back
17 as recorded above.

18 THE WITNESS: They're healthy nerves
19 which can conduct pain. This is one of the main
20 findings.

21 BY MR. THOMAS:

22 Q. Okay. But again, there's nothing
23 about those that allow you to state that those
24 nerves were in fact reacting in a way to cause pain
25 in a patient while the mesh was implanted?

1 A. The point of the picture is to
2 show that that tissue is sensitive, so it can sense
3 pain.

4 Those nerve branches are not directly
5 affected or at least one may, but the others are
6 not directly affected by the mesh.

7 The point is that tissue around it is
8 innervated, so if you get a formation, if you get
9 distortion, mechanical compression, then it can
10 sense pain.

11 Q. Okay. Page 67 of your first
12 report, Figure Set 13a, you're talking about the
13 Prolene degradation layer.

14 Do you know if this is TVT or TVT-O?

15 A. No.

16 Q. Do you know from what case this
17 comes?

18 MR. ORENT: Objection.

19 THE WITNESS: One of the consolidated
20 cases.

21 It's so similar to this study, which I
22 think our scientists did in 87. I mean, even the
23 arrow there is so similar.

24 BY MR. THOMAS:

25 Q. So all of these images are from

1 the consolidated cases through 72, and our experts
2 have these images, correct?

3 A. Images -- they have slides.

4 Q. Slides, that's what I meant.

5 A. Yes.

6 Q. I've talked to you, you've been
7 talked to at length about these images in prior
8 cases. Is there anything new and different about
9 what's expressed in these images that you haven't
10 seen before?

11 A. It is exactly what I described in
12 the published papers and previous reports. Exactly
13 all, everything is the same.

14 Q. For the other cases that you begin
15 on 73, you had images from additional TVT cases.
16 Do you know whether those are TVT or TVT-O?

17 A. No.

18 MR. ORENT: Objection.

19 BY MR. THOMAS:

20 Q. If you go to page 72, please?

21 A. Yes.

22 Q. On page 72, you show an empty
23 space of detached core on the right image. And a
24 separated degradation bark. The empty space means
25 that the polypropylene dropped out of the image?

1 A. Not image, slide.

2 Q. Slide, I'm sorry. Thank you.

3 A. It came detached and displaced.

4 Q. Okay. And left what you have
5 described as the bark behind?

6 A. Yes, that's correct.

7 Q. All right. Now, if you go to the
8 next page, page 73, again, additional TVT cases you
9 show an image where you show the polypropylene
10 still in place, correct?

11 A. Yes. So now there is a
12 separation. The core separated from the bark, but
13 the core didn't detach completely and floated away.
14 It's still close, but there was a split.

15 Q. And this is detached as a part of
16 the sample preparation process, correct?

17 MR. ORENT: Objection.

18 THE WITNESS: I don't know when it
19 became detached. During surgery or during
20 sectioning or during processing of the specimen.

21 BY MR. THOMAS:

22 Q. Didn't happen in vivo, didn't
23 happen in the body?

24 A. No. I suspect it doesn't happen
25 that often. I very rarely see the bark actually in

1 the tissue, being displaced in the tissue away from
2 the fibers.

3 Q. Have you studied how mechanically
4 that happens?

5 A. It just breaks off. There is a
6 shear force, a breaking force.

7 Q. When you say a shear force, does
8 it shear off at the point where -- at about five
9 microns as the degradation ceases?

10 A. It shears off in the interface
11 between degraded and non-degraded.

12 Q. That's my point. Let's see if we
13 can agree with this. We're dealing with visual
14 observations here, correct?

15 A. Yes, that's correct.

16 Q. And is it fair to understand with
17 respect to the images on page 73, where you show
18 detached core and degradation bark separated, are
19 you telling me that the detached core no longer has
20 a bark on it?

21 A. They have a really thin layer of
22 degraded material. Because the bark itself is not
23 uniform. There is a higher degree of degradation
24 on the outside and then smaller, smaller, smaller,
25 smaller, smaller.

1 Q. Right.

2 A. And then the degradation blends
3 into not degraded polypropylene.

4 Q. Right.

5 A. So at certain point these micro
6 cracks, and mono cracks, they cannot go into this
7 completely solid material, so it shears off
8 somewhere there.

9 I don't know if it's right at the end
10 of them, close to them or how far they are. So
11 there might be a layer of degraded polypropylene on
12 the core. How thick it is, I wouldn't know.

13 Q. It's too small to measure by your
14 technique?

15 A. That's correct.

16 Q. And your best estimate is that the
17 degradation bark that appears, as you've described
18 it in 73, is much as five microns?

19 A. This is thinner. By looking at
20 it, it is around two microns.

21 Q. Now what you show on page 75,
22 again from additional TVT cases, are the cracks
23 which you believe to be oxidized polypropylene,
24 correct?

25 A. I don't believe -- I know.

1 Q. Okay. And Figure Set 13i, do you
2 know if this is a TVT or TVT-O?

3 A. No.

4 Q. Do you know how long this was in
5 the body?

6 A. Certainly more than a year.

7 Q. Why do you say that?

8 A. It's relatively thick. So if I
9 check here where it's less tangential, this is the
10 thickness, so it's definitely more than a year.

11 Q. When you devised your experiment
12 to intentionally oxidize polypropylene, did you
13 look at any methods that would allow you to
14 intentionally oxidize polypropylene in a time of
15 less than a year and a half?

16 A. No, I didn't take them out.

17 Q. You misunderstood my question.

18 Did you attempt to identify any kind of
19 chemical recipe that would allow you to
20 intentionally oxidize Prolene more quickly than a
21 year and a half?

22 A. No.

23 Q. Why not?

24 A. I'm busy enough with other things.

25 Q. Okay.

1 A. And I figure I just leave it long
2 enough, soon enough it will form and I will see
3 which would -- in which fluid the bark is thicker.

4 Q. We talked before, I believe at
5 trial, about xylene and that you were conducting a
6 test to determine the extent to which xylene
7 impacted Prolene polypropylene; do you remember
8 that?

9 A. Yes, I do.

10 Q. You told me, I believe, that you
11 were currently testing xylene to determine whether
12 xylene would impact Prolene polypropylene. Are you
13 still conducting that test?

14 A. It's in the same set of jars. One
15 of the jars contains xylene.

16 Q. Is that the only test that you're
17 doing with xylene?

18 A. Well, previously I did testing for
19 processing. So new mesh was put in regular xylene
20 solution for time when it happens during tissue
21 process.

22 Q. Did you produce that to me in the
23 jump drive Exhibit 4.

24 A. No, these are the images of new
25 pristine mesh. So this mesh had been through

1 xylene.

2 Q. Okay. Did you do any other
3 testing of pristine mesh impact on xylene over a
4 period of time?

5 A. No. These only two. I did
6 experiment for our routine processing, routine
7 exposure to xylene, and then I started this
8 experiment.

9 I was testing it within month or two
10 after it became exposed. I was thinking maybe it
11 would get dissolved; it didn't. But the long-term
12 effect will be studied later on together with other
13 solutions.

14 Q. When you put the pristine mesh
15 through the sample preparation process, did you
16 perform any analytical chemistry on the mesh to
17 determine the extent to which xylene may have
18 altered the chemical structure of polypropylene?

19 A. No.

20 Q. On page 84?

21 A. Yes.

22 Q. Is page 84 another image of what
23 we had talked about at length on page 83?

24 A. No, this is a different case.
25 This is a case consolidated case. This is

1 appearance of case from -- you can see the name of
2 the patient.

3 Q. Okay. So this is -- strike that.

4 Did you do any analysis for bark on the
5 mesh depicted in Figure 16a?

6 A. It's embedded in histology. It's
7 there. I mean --

8 Q. Have you ever done it?

9 A. I didn't do anything specific.
10 It's embedded in histology. I can pull the slide
11 and take picture of the bark.

12 But again, this is a St. Michael's
13 patients, I'm not comfortable disclosing or giving
14 pictures specifically for trial or anything else.
15 I can tell you that I saw the bark.

16 Q. So, Figure 16b on page 84 is
17 cracking on the surface of TVT mesh fibers. And
18 this is from the consolidated cases for patient
19 Dameron; is that correct?

20 A. That is correct.

21 Q. And these are the tissue samples
22 that you show on 84 that you had available to you?

23 A. Yes.

24 Q. And they had been stored in
25 formalin?

1 A. No. We received it dry. Your
2 expert was there.

3 Q. Okay.

4 A. It was jar without formalin.

5 Q. Do you know whether it was in
6 formalin?

7 A. I don't. Probably it was at one
8 time, it leaked out but... that's my assumption.

9 Q. You do know how long this was in
10 the body?

11 A. No.

12 Q. And obviously you don't know how
13 it was handled before it got to you, correct?

14 A. No.

15 EXHIBIT NO. 5: Study Entitled "Safety
16 Considerations for Synthetic Sling
17 Surgery" in which Dr. Vladimir Iakovlev
18 appears as an author.

19 BY MR. THOMAS:

20 Q. Doctor, I'm going to hand you
21 what's been marked as deposition Exhibit No. 5.

22 A. Yes.

23 Q. Deposition Exhibit No. 5 is a
24 review study in which you appear as an author --

25 A. Yes.

1 Q. -- entitled, "Safety
2 Considerations for Synthetic Sling Surgery".

3 I know Dr. Blaivas. Who is Dr.
4 Purohit?

5 A. I don't know. It's a team of
6 urologists and fellows working with Dr. Blaivas.

7 Q. Okay. Did you consult with Dr.
8 Blaivas on the content of this article?

9 A. Well, we wrote it together.

10 Q. And that's my point. Did you work
11 with this whole team in writing the article?

12 A. Yeah. We were changing, everybody
13 was contributing. It was changed several times,
14 redacted and...

15 Q. Did you work with any individual
16 specifically, or did you write your own piece and
17 just look after your own section of the article?

18 A. Oh, it's a joint effort. I mean,
19 the manuscript consult, everybody contributes, puts
20 one piece there, puts one piece there.

21 It's been changed and then editorial
22 office changes and then we change back and then so
23 forth. By the end of the day each single word may
24 be coming from a different person.

25 Q. How many drafts did this Exhibit 5

1 go through?

2 A. Five, six.

3 Q. Do you still have those drafts?

4 MR. ORENT: Objection.

5 THE WITNESS: Yes, I do. But I mean
6 this is more of a delicate issue because there are
7 many authors involved and there is research
8 produced information, and it's a work in progress.

9 What became public is what we see right
10 in front of us. What we decided to be correct to
11 be exposed to the public.

12 BY MR. THOMAS:

13 Q. Other than the journal itself, was
14 anybody else involved in the preparation of
15 Exhibit 5?

16 A. What do you mean?

17 Q. Did you have any contribution from
18 any other source other than the authors that were
19 listed in the preparation of the article?

20 A. Everybody listed as authors,
21 everybody who contributed is here. Well, editorial
22 office was working with it also.

23 Q. And who did you work with at the
24 editorial office?

25 A. I don't remember now.

1 Q. Okay.

2 A. I mean, they send their paper,
3 they said, okay, this revision needs to be
4 reviewed, please check this, please check that,
5 they suggest some changes, mainly just style. Very
6 strict regarding style.

7 Q. You said something earlier today,
8 I want to make sure I understand. In this
9 document, there is reference to work that you have
10 done on different meshes in the medical-legal
11 setting.

12 I thought I understood you to say that
13 you didn't use the slides that were provided to you
14 by Dr. Kreutzer, but that you cut new slides from
15 existing blocks and conducted your analysis on
16 those new slides; is that correct?

17 A. For some cases, I received only
18 slides, stained and unstained. For some cases I
19 received blocks. As far as I remember, it's been
20 long time.

21 So I could either use unstained slides
22 which came together with stained slides, or I could
23 ask my lab to do recuts from the blocks which were
24 made before me.

25 Q. All right. So, your best

1 recollection it was a mixture of previously
2 existing slides or recuts from this mesh that you
3 had obtained from Dr. Kreutzer, correct?

4 A. Yes.

5 Q. Is the same thing true with your
6 other mesh specimens that were involved in
7 medical-legal field, that on some occasions you'd
8 use existing slides and some occasions you'd use
9 recuts or you'd have recuts made of existing
10 blocks?

11 A. That's correct. Depends on
12 situation.

13 Q. I assume you stand by all the
14 findings in this report, correct?

15 A. It's not findings; this report is
16 a review. So it's more based on the other papers.

17 Q. Okay?

18 A. The only thing which was produced
19 in this paper from us personally was figures.

20 Q. Let's go to one of those figures
21 on page 4.

22 A. You mean the table?

23 Q. Table two on page 4?

24 A. Yes.

25 Q. And this review paper, in

1 reporting longer-term complications, reports pain
2 greater than six weeks for either retropubic or
3 transobturator tape slings at 3.5 percent, correct?

4 A. Which line?

5 Q. Third from the bottom, longer-term
6 complications. Do you see it, for refractory pain
7 greater than six weeks?

8 A. So the incidence range is from 4.1
9 to 30 percent.

10 Q. The complications percentage of
11 patients that report refractory pain greater than
12 six weeks is 3.5 percent, correct?

13 A. What I see is 4.1 to 30 percent.

14 Q. Well --

15 A. Third line from the bottom.

16 Q. I understand that's the mean and
17 the range, correct?

18 A. Yes.

19 Q. 4.1?

20 A. Sorry, 4.1 is mean. Yes, you're
21 correct. I need my glasses.

22 So this is -- the range is from 0 to
23 30 percent.

24 Q. But the average -- excuse me --
25 the percentage of patients at 7,084 that report

1 pain greater than six weeks, is 247 or 3.5 percent,
2 correct? Is that right?

3 A. Yes and no. So this is a review
4 of previously published studies. So the quality of
5 the studies is different, methodology is different.
6 But when you check them, the pain over six weeks is
7 reporting anywhere from 0 to 30 percent.

8 Q. Okay.

9 A. With a mean, or average
10 4.1 percent.

11 Q. But these numbers are correct,
12 aren't they?

13 A. Well, from what we extracted at
14 that stage from the papers, that's what we have.

15 Q. Okay. You went out and tried to
16 obtain complication rates for retropubic or TOT
17 slings, didn't you?

18 A. Yes. The whole paper is just for
19 slings.

20 Q. And as a part of looking at
21 long-term pain which is greater than six weeks, you
22 looked at 7,084 patients, correct?

23 A. No, we didn't. The papers in
24 combination.

25 Q. I understand. But you gathered

1 papers that looked at over 7,000 patients?

2 MR. ORENT: Objection.

3 THE WITNESS: That's what it says
4 there, yes.

5 BY MR. THOMAS:

6 Q. And in gathering the papers, who
7 was in charge of picking which studies you looked
8 at?

9 A. That part -- it's not a study; it
10 is a review.

11 Q. I apologize.

12 A. That part of the review was done
13 mainly by urologist.

14 Q. Do you know who that was?

15 A. It's a team working with Dr.
16 Blaivas.

17 Q. So the urologist, the clinicians,
18 are the people who are responsible for identifying
19 the studies to identify the complication rates?

20 A. That's correct.

21 Q. And through their best efforts,
22 they identified a percentage of patients that have
23 pain more than six weeks at 3.5 percent, correct?

24 A. That was an estimate of a minimal,
25 a minimum number. So this is the bottom line. So

1 it's minimum of 3.5 percent of the patients will
2 develop chronic pain.

3 Q. Okay.

4 A. Which is -- probably doesn't say
5 right away, but that was the minimum. It wasn't
6 that we were implying that it's a true number.

7 Q. Do you know how many, for how many
8 of those 3.5 percent that the pain was ultimately
9 resolved?

10 A. Again, 3.5 percent was minimum
11 number.

12 Q. I understand. But for some of
13 those people they were cured of the chronic pain,
14 weren't they?

15 MR. ORENT: Objection.

16 THE WITNESS: After mesh removal?

17 BY MR. THOMAS:

18 Q. Or for whatever treatment?

19 MR. ORENT: Objection.

20 BY MR. THOMAS:

21 Q. Do you know that?

22 A. No, I don't know. I don't think
23 it was in the published literature.

24 Q. That's fine. Do you know whether
25 the urologist group who were looking at the mesh

1 complications looked to see how many people had
2 their pain resolved by surgery or some other
3 treatment?

4 A. Those papers are reviews. Most of
5 them didn't provide that information. They just
6 provided numbers for complications.

7 Q. Did you do a literature search
8 yourself to determine the extent to which long-term
9 complications of chronic pain were resolved by
10 surgery or other treatment?

11 A. Not to answer that specific
12 question. Again, I mean, I only can read what is
13 published. Because studies don't concentrate,
14 don't focus on this question; I cannot get an
15 answer.

16 Q. Well, this was your group's best
17 effort at presenting, in a reviewed paper, the rate
18 of complications for long-term pain, correct?

19 MR. ORENT: Objection.

20 THE WITNESS: Yes, you're correct.

21 BY MR. THOMAS:

22 Q. Thank you.

23 A. But the question is that if I made
24 an effort to look for something which is barely
25 ever published; that's why I answered that it's

1 specifically to that question, would be difficult
2 to do.

3 -- RECESS AT 4:08 --

4 -- UPON RESUMING AT 4:15 --

5 BY MR. THOMAS:

6 Q. Doctor, let's go back to Exhibit
7 No. 5, page 5. I asked you about the wrong chart.
8 I asked you about the chart on page 4.

9 The chart on page 4 does retropubic and
10 obturator slings. The one on page 5 is limited to
11 retropubic slings; do you see at the top?

12 A. Yes.

13 Q. And retropubic slings are what TVT
14 slings are, correct?

15 A. Yes.

16 Q. And the long-term refractory pain
17 greater than six weeks reported by your group is
18 1.8 percent, correct?

19 A. Yes, but it's not reported by our
20 group.

21 Q. Collected by your group?

22 A. Collected from other papers by our
23 group, yes.

24 Q. And as a part of that, the group
25 looked at studies reporting on about 2,328

1 patients, correct?

2 A. Yes.

3 Q. Okay. For the slide on page 82,
4 about the -- 83, I'm sorry. About the image of the
5 TVT mesh fibers immediately after surgery removal?

6 A. Yes.

7 Q. Did you submit any histology to
8 the journal for publication?

9 A. For this case?

10 Q. For the journal. For --

11 A. Which one?

12 Q. In one of the studies you have the
13 image of that --

14 A. It's --

15 Q. Is it the other journal?

16 A. Yes, this one.

17 Q. I'll come back to that.

18 A. You mean histology of that
19 specific case?

20 Q. Yes.

21 A. No.

22 Q. Have you shared the histology of
23 that specific slide with anybody period?

24 MR. ORENT: Objection.

25 THE WITNESS: No.

1 BY MR. THOMAS:

2 Q. So you're the only one that's ever
3 looked at it?

4 A. Pardon?

5 Q. You're the only one that's ever
6 looked at it?

7 A. Yes. I don't think I have
8 pictures, I didn't take pictures.

9 Q. Okay. Why not?

10 A. What for?

11 Q. Okay.

12 EXHIBIT NO. 6: Article entitled,
13 "Degradation of Polypropylene in Vivo:
14 A Microscopic Analysis of Mesh
15 Explanted from Patients."

16 BY MR. THOMAS:

17 Q. Let me show you what's been marked
18 as deposition Exhibit No. 6.

19 Deposition Exhibit No. 6 is an article
20 entitled, "Degradation of Polypropylene in Vivo: A
21 Microscopic Analysis of Mesh Explanted from
22 Patients". That was just recently released,
23 correct?

24 A. That is correct.

25 Q. And you worked with Dr. Guelcher

1 and Dr. Bendavid on this?

2 A. Yes.

3 Q. Did you receive any funding for
4 your work in Exhibit 6?

5 A. No.

6 Q. Did Dr. Guelcher or Dr. Bendavid
7 receive any funding for their work on Exhibit 6?

8 A. No. The work actually was done
9 mainly by me. Dr. Guelcher and Dr. Bendavid just
10 contributed to the drafting of the manuscript.

11 Q. What did Dr. Guelcher contribute
12 to the manuscript?

13 A. The drafting of the manuscript, we
14 discussed mechanism of degradation, mechanically
15 how it happens, oxidation and other aspects.

16 Q. Do you view Dr. Guelcher as
17 authoritative on the issue of oxidative
18 degeneration -- excuse me.

19 Do you view Dr. Guelcher as
20 authoritative in the area of oxidative degradation
21 of polypropylene?

22 A. He's a bio engineer. He works in
23 the area.

24 Q. How do you feel about him? Do you
25 view him as authoritative in the field?

1 MR. ORENT: Objection.

2 THE WITNESS: I'm not sure if I can
3 answer that question.

4 BY MR. THOMAS:

5 Q. Okay?

6 A. He's a specialist who works in the
7 area and works in the field.

8 Q. At any time, have you relied upon
9 Dr. Guelcher to tell you, chemically, how
10 polypropylene oxidizes?

11 A. No. In fact, it wasn't my purpose
12 to answer the question how it oxidizes. It only
13 describes that it does oxidize.

14 Q. So what role did Dr. Guelcher play
15 in the preparation of Exhibit 6?

16 A. Drafting of the manuscript, mainly
17 the discussion part. He also suggested at one
18 point when we started working on this, doing a
19 myeloperoxidase stain. Again, in relation to
20 oxidative degradation.

21 Q. What role did Dr. Bendavid have in
22 this study?

23 A. Well, he actually brought me to
24 this mesh field and he supplied, or some samples
25 came from Shouldice Hospital, where he worked. And

1 he also helped drafting the manuscript.

2 Q. In terms of the data gathering and
3 the conclusions contained herein, is this basically
4 your work?

5 A. For the most part.

6 Q. And I hate to ask you again, but
7 what data gathering or conclusions did Dr. Guelcher
8 or Dr. Bendavid provide?

9 A. Dr. Guelcher didn't gather any
10 data. As you can read the manuscript or paper,
11 it's all histology.

12 Q. Okay?

13 A. So I've been collecting data and
14 analyzing the samples.

15 But Dr. Bendavid contributed with idea
16 of degradation and contributing some samples,
17 hernia samples, and Dr. Guelcher contributed in
18 drafting the manuscript and also suggesting
19 myeloperoxidase stain and suggesting what is the
20 mechanism of degradation.

21 But the histology itself, data
22 collection and analysis, was done by me.

23 Q. As part of the preparation of this
24 paper, did you and your coauthors discuss
25 intentionally oxidizing polypropylene to see if it

1 would hold stain?

2 A. No. This paper was started, or
3 most of the data was collected even before I
4 learned about this simulation model. So it wasn't
5 a part.

6 Q. Did you ever discuss with Dr.
7 Guelcher different ways to intentionally oxidize
8 polypropylene?

9 A. Later on. I mean, the manuscript
10 was mainly written already and then we started
11 discussing plans for the future. And then that's
12 how I used the paper he suggested as a recipe for
13 simulation.

14 Q. Okay. So Dr. Guelcher suggested
15 to you the paper that you used for the simulation?

16 A. I think so.

17 Q. Okay?

18 A. Maybe I saw it before, but he
19 pointed that, that's the recipe he was using as
20 well.

21 Q. Got it. Is Dr. Guelcher involved
22 in your experimental work on the samples that
23 you're now storing?

24 A. No. I mean, I had my own samples.
25 His contribution to this work is that I ask him

1 what he's using, or I don't remember exactly how
2 the conversation started, and he said that he's
3 using recipe from that specific paper.

4 Q. I see.

5 A. And I used it. We didn't have
6 exchange of the samples, or testing of each other's
7 samples.

8 Q. So you have never analyzed the
9 samples that he tested?

10 A. No, never seen those.

11 Q. And you know that he's exposed
12 samples to five and six weeks' worth of exposure?

13 A. I do know that.

14 Q. Okay.

15 A. I do know that.

16 Q. Have you requested to look at
17 those or test those or analyze those in any form?

18 A. There was a discussion. I don't
19 know if I said that I don't want to do it because I
20 have my own and I believe it needs to be a year.

21 Or maybe they used all their samples
22 for SEM, and they didn't have anything left. But
23 at that time the decision was to wait for my
24 samples to become mature.

25 Q. Okay. Did you submit this article

1 to multiple journals?

2 A. There was submission to at least
3 two journals and the answer was really quick, next
4 day. They said no, it's not in our scope. And I
5 was aiming at really high impact like Nature, so...

6 Q. Nature turned it down?

7 A. (Witness nods).

8 Q. Okay.

9 A. Are you surprised?

10 Q. And so is the Journal of
11 Biomedical Materials the only other journal that
12 reviewed it?

13 MR. ORENT: Objection.

14 THE WITNESS: Yeah, this is my usual
15 approach. For all my papers I start really high
16 impact journal, hope for the best, and then go
17 from there.

18 BY MR. THOMAS:

19 Q. Now, was there a peer-review
20 process of this article?

21 A. Yes. They ask for revisions, I
22 did revisions, then we drafted it.

23 Q. How many drafts did you have of
24 Exhibit 6?

25 A. We had one revision, one large

1 revision. Part of the manuscript removed tables.

2 MR. ORENT: I object to this whole line
3 of questioning. It's outside of the scope of the
4 expert testimony, and moreover I think there's a
5 public policy interest in maintaining the integrity
6 of the editorial board process of the journals.

7 BY MR. THOMAS:

8 Q. Do you still have your first
9 draft?

10 MR. ORENT: Objection.

11 THE WITNESS: I can't answer that.

12 BY MR. THOMAS:

13 Q. You can't?

14 A. (Nods).

15 Q. Why?

16 A. It goes to the issues Mr. Orent
17 just mentioned.

18 Q. Okay. So have you maintained a
19 file on the preparation, the data you gathered, the
20 submission process and the peer-review process for
21 Exhibit 6?

22 A. Did I?

23 Q. Yes.

24 MR. ORENT: Objection.

25 THE WITNESS: Yes, I did.

1 BY MR. THOMAS:

2 Q. I just ask you to maintain that
3 file and either I'll get it or I won't. Just don't
4 do anything to it; that's all I ask.

5 Just so I can short cut this. Is it
6 fair to say you're not going to answer any more
7 questions about the generation, drafting, peer
8 review, submission and publication of the article?

9 A. It was a standard process. There
10 was nothing unusual about it.

11 Q. But in terms of the details of it
12 you're not going to answer any questions about
13 that?

14 A. No. I can tell that you there was
15 nothing unusual.

16 Q. I understand. If you'll turn to
17 page 2, Table 1 is the sample and patient data?

18 A. Yes.

19 Q. And under "Slings", it says that
20 you have 28 TVT or TVT-Os; do you see that?

21 A. That is correct.

22 Q. Do you know the breakdown between
23 TVT and TVT-O?

24 A. No.

25 Q. Okay. Do you know whether any of

1 them are machine cut or laser cut?

2 A. No.

3 Q. You have four Prolift products; do
4 you see that?

5 A. Yes, I do.

6 Q. And then a number of hernia mesh
7 cases, correct?

8 A. That is correct.

9 Q. Of the 69 slings that you
10 analyzed, how many were medical-legal cases?

11 A. The breakdown was about
12 70 percent. I cannot tell you exact number. But
13 roughly, it's for the whole set was 70 percent
14 medical-legal and 30 percent hospital cases.

15 And not necessarily St. Michael's.
16 They were coming from different hospitals.

17 Q. Okay. Is it fair to say if
18 they're undetermined that they're not medical-legal
19 cases?

20 A. At least 70 percent were
21 medical-legal.

22 Q. I understand that, but I'm trying
23 to break it down further to find out which ones
24 were medical-legal and which ones were not.

25 And you have 45 hernia cases that you

1 identify as undetermined. I'm making an assumption
2 that because they're undetermined hernia cases that
3 they're probably not medical-legal cases; is that a
4 fair assumption?

5 A. Some of them are medical-legal.

6 Q. What percentage of the
7 undetermined hernia cases were medical-legal; do
8 you know?

9 A. The undetermined are probably all
10 non-medical-legal. I don't think medical-legal is
11 undetermined.

12 Q. That was my point?

13 A. Yes.

14 Q. So when we're making the
15 calculation of the 70 percent, is it safe for us to
16 exclude -- or strike that.

17 Is it safe for us to include the 45
18 undetermined hernia cases in the 30 percent of the
19 non-medical-legal cases?

20 A. Yes, we can do that right away.

21 Those would be non-medical-legal cases.

22 Q. Okay.

23 A. There could be some potentially
24 medical-legal cases when I receive a specimen but I
25 have not received a history. They say, hold on to

1 this -- may be medical-legal case later on.

2 Q. Okay?

3 A. So it's not hard number.

4 Q. Right.

5 A. But it's a ballpark.

6 Q. For the Ethicon TVT, TVT-O of
7 those 28 how many of them are medical-legal?

8 A. At least 80 percent.

9 Q. Perhaps more?

10 A. Possibly more.

11 Q. And included within the 28 Ethicon
12 TVT and TVT-O are the cases that you received from
13 Dr. Kreutzer, correct?

14 A. Yes. Most of St. Michael's cases,
15 when I had a record, were actually TVT. So I don't
16 know for whatever reason most of those excised at
17 St. Michael's were TVT.

18 Q. Okay. And in addition, you had
19 new TVT and TVT-O cases since Dr. Kreutzer, and
20 those would be included in this article as well?

21 A. Yes.

22 Q. So, for example, the Edwards case
23 would probably be in this?

24 A. Yes, it would be in there. I
25 received the Edwards case before I received

1 specimen from Dr. Kreutzer.

2 Q. Okay. Interesting.

3 On page 3 of this study, you talk about
4 measuring the degradation layer's thickness?

5 A. Yes.

6 Q. And you say a set of 23
7 mid-urethral slings was the largest uniform group
8 that fulfilled your criteria. Is that the slings
9 that you got from Dr. Kreutzer?

10 A. Most of them came in that set of
11 samples.

12 Q. All right. Tell me how you
13 physically measure the thickness of the stained
14 layer with the eyepiece micrometer?

15 A. I would find fibers which are cut
16 as perpendicular as possible and measure bark
17 thickness on at least two occasions.

18 And then measure -- I try to find
19 another fiber, measure again, and then take median
20 number, the most frequent I'm getting.

21 Q. Do you have the data that you
22 collected on those measurements?

23 A. Yes, I do.

24 Q. Okay.

25 A. I mean, you have it on the --

1 Q. Is it on the thumb drive?

2 A. It's on the thumb drive. And you
3 saw it before at various depositions.

4 Q. Thank you. I don't want to redo
5 that.

6 And when you do the eyepiece micrometer
7 and you measure, to what level can you measure?

8 A. Initially, I had one micrometer.
9 It was graded only to one micrometer. Now, I have
10 little bit better so I can measure up to half a
11 micrometer.

12 Q. When you were doing this study,
13 were you measuring at one micrometer?

14 A. I was rounding to one micrometer;
15 it was an older eyepiece.

16 Q. So the data in the study, you're
17 rounding your findings to the closest micrometer?

18 A. Yes. To the full number.

19 Q. Did you round up always?

20 MR. ORENT: Objection.

21 THE WITNESS: No, it depends. If it's
22 less than a half of the next gradation, it would go
23 to the lower, but that's the usual rule for --

24 BY MR. THOMAS:

25 Q. Okay, that's fine. And then when

1 you had two together -- so you had a total of four
2 measurements?

3 A. I would aim at four measurements
4 at least.

5 Q. And each one of those would go
6 through some rounding process?

7 A. Yeah, I mean, the accuracy of
8 measurement was within half a micrometer plus or
9 minus.

10 Q. Okay. Now --

11 A. But it would be random, up and
12 down, up and down, so they would constantly change.

13 Q. Now, in some places in images we
14 looked at today, we didn't find any bark, correct?

15 MR. ORENT: Objection.

16 THE WITNESS: This is not correct. We
17 could not see it in the images. I can tell you
18 that in some specimens I did not see bark.

19 BY MR. THOMAS:

20 Q. How do you report that?

21 A. I report that I don't see it. I
22 have cases when I reported that I don't see a bark.

23 Q. And you reported here that you had
24 two specimens where the degradation layer was not
25 visible where a hernia mesh and a sling were

1 removed at three and ten months.

2 Are those the only two times you
3 haven't been able to see a bark?

4 A. At that time, the only two. Since
5 then I've seen a couple of more cases where I
6 couldn't identify bark.

7 Q. Any of those medical-legal cases?

8 A. No, I think it was all hernia
9 meshes, not medical-legal cases.

10 Q. Do you have those slides
11 available?

12 MR. ORENT: Objection.

13 THE WITNESS: Yes, I do, but they are
14 of patients.

15 BY MR. THOMAS:

16 Q. You can't produce those to me if I
17 asked you for them?

18 A. I can't produce them.

19 Q. Did the slides where there was no
20 degradation bark, if you will, present contain
21 inflammation?

22 A. Yes, they did.

23 Q. Were they removed because of pain?

24 A. Yes. I think one of them was
25 removed for erosion with pain. The other one, the

1 hernia mesh, was removed just for pain.

2 Q. On page 6 of the study, you
3 describe that you use transmission electron
4 microscopy --

5 A. That's correct.

6 Q. -- to study the ultra structural
7 organization of the degraded layer in
8 cross-sections?

9 A. That's correct.

10 Q. Did you use the TEM to study any
11 TVT device?

12 A. One. It was one Ethicon device,
13 TVT or Prolift, I don't remember. I think it was a
14 TVT.

15 Q. Have you produced that work to us
16 before?

17 A. It's a St. Michael's Hospital
18 patient.

19 Q. Okay. So, is it fair to
20 understand that the only transmission electron
21 microscopy analysis that you've done on an Ethicon
22 mesh is the St. Michael's patient that you can't
23 produce to us?

24 A. Well, it was a part of research.
25 So if it was included in images, it was included as

1 part of research project.

2 Q. Well, have you produced that to us
3 before?

4 A. I don't know.

5 Q. Okay. But just to make sure I got
6 a clean answer. In all the work that you've done
7 on all the Ethicon meshes, the only Ethicon mesh
8 that you've analyzed by transmission electron
9 microscopy is a mesh of a St. Michael's patient
10 that's either a TVT or a Prolift, you don't know
11 which?

12 A. Now I'm not sure if it was St.
13 Michael's or it was a medical-legal case. I don't
14 remember now.

15 Q. Okay?

16 A. I would have to check, but if it
17 was, it was the only case. I could do only one
18 case of Ethicon mesh by transmission electron
19 microscopy.

20 Q. And why have you not conducted
21 transmission electron microscopy on other meshes?

22 A. There was no need. It is a really
23 cumbersome, difficult and --

24 Q. Does St. Michael's have that kind
25 of equipment?

1 A. Yes, we do. Otherwise, I wouldn't
2 be able to do it. It's really expensive to do it
3 somewhere outside.

4 Q. Did you have to pay St. Michael's
5 to do this?

6 A. No, it's just part of our academic
7 work.

8 Q. Are you able to do this yourself
9 or does somebody have to do it for you?

10 A. I'm trained to do transmission
11 electron microscopy. I mean, technicians prepare
12 slides. It's usual, the same as for histology.
13 But I do examination myself.

14 Most of the transmission electron
15 microscopy samples are with hernia meshes.

16 Q. Page 10 there is a discussion of
17 the clinical significance of polypropylene
18 degradation?

19 MR. ORENT: Are we going back to the
20 report or saying on the study?

21 MR. THOMAS: I'm on the study, sorry.

22 THE WITNESS: Yes.

23 BY MR. THOMAS:

24 Q. Page 10 on Exhibit 6, "Clinical
25 Significance of Polypropylene Degradation".

1 Who drafted this section?

2 A. Mostly me, partially my coauthors.

3 Q. Dr. Bendavid?

4 A. Yes. And well, mostly Dr.

5 Bendavid. I mean, I drafted most of it, but I was

6 getting some corrections or changes, and the

7 changes were coming mostly from Dr. Bendavid.

8 Q. Exhibits 5 and 6, you stand by the
9 findings stated in each of those articles?

10 A. Yes, I am.

11 Q. Do you have depositions scheduled
12 in the next month?

13 A. I'm not sure if I can disclose
14 that.

15 Q. Do you have trial responsibilities
16 in the next month?

17 A. Pardon?

18 Q. Do you have any trial
19 responsibilities in the next month?

20 A. No, I don't think so.

21 Q. Your next trial is a December
22 trial with Ethicon?

23 A. I'm not sure if I can disclose
24 that either.

25 Q. Are you choosing not to?

1 A. There might be more and earlier, I
2 don't want to disclose that. I'm not sure if I
3 can, if I legally can disclose it.

4 I mean, if it's not for Ethicon cases.
5 For Ethicon I would disclose, but if it's not then
6 I cannot disclose.

7 MR. THOMAS: Counsel, there's no legal
8 prohibition for him saying it?

9 MR. ORENT: You can answer.

10 THE WITNESS: They said that --

11 MR. ORENT: Wait, hold on. They said
12 is not an answer. So any communications that
13 you've had are covered by a privilege. So what
14 he's asking specifically are, if anything is firm
15 in terms of a date that you know of, so --

16 BY MR. THOMAS:

17 Q. For depositions or trial?

18 MR. ORENT: For depositions or trial,
19 not any communications about we might do this or
20 might do that. But anything firm that you know you
21 have a date set for.

22 THE WITNESS: Then everything is
23 changing. I have a set date one deposition. But
24 the rest is still in the air.

25

1 BY MR. THOMAS:

2 Q. Do you have any set dates for any
3 trials between now and the Ethicon trial?

4 A. No. Again, nothing set firmly.

5 Q. Okay.

6 MR. ORENT: Just a sec. In addition to
7 that, I think in the Cantrell matter I've been
8 working with Kelly Crawford to schedule, I would
9 imagine that would be within the next month.
10 That's an Ethicon case, obviously.

11 MR. THOMAS: Yes, I know about that.

12 Hang on. Getting close to the end.

13 -- OFF THE RECORD DISCUSSION --

14 BY MR. THOMAS:

15 Q. Doctor, I'm told that the
16 information supplied to us concerning the eyepiece
17 micrometer measurements of the bark layers is
18 expressed in a single value as opposed to the four
19 individual measurements?

20 A. No, it's a median, I told you
21 that, then I pick median value out of four.

22 Q. Okay.

23 A. It is described in the paper. So
24 the volume which goes for analysis is a median one,
25 which is more frequent.

1 Q. Do you have the four measurements
2 that you made or did you just pick the -- do you
3 have that as a part of your data set?

4 A. I just measure them and right
5 there I know how frequent is this measurement or
6 that. So I don't have to put in the paper.

7 Q. Did you write down or keep a copy
8 of the four individual measurements that you made
9 of the --

10 A. No, no. The methodology is check
11 four spots. I see three, four, four, four, then
12 four is the winner, so then four goes in the
13 record.

14 Q. Did you produce your bills today
15 for the time that you spent in this case?

16 A. In this case?

17 Q. In this case?

18 A. Oh, in this. I had billing done
19 for the -- for the report, it's in the folder.

20 Q. Do you recall how much time and
21 money you've spent on preparing the report in this
22 case, Exhibit 3 and 4?

23 A. No, I don't.

24 Q. The invoice that you produced to
25 us on a thumb drive suggests that you have a

1 balance, professional services August 14th,
2 August 24th for a total of \$8,550 --

3 A. Sounds right.

4 Q. -- is that right?

5 Doctor, I don't see -- I see general
6 part text revision; what does that mean?

7 A. Revision of the general part.

8 Q. General party report?

9 A. Yes.

10 Q. This report is the first time that
11 you reviewed any Ethicon documents or Ethicon
12 depositions, true?

13 A. No, there was another case.

14 Q. I didn't see it in any of your
15 reports before where you reviewed Ethicon
16 depositions and Ethicon documents?

17 MR. ORENT: One moment.

18 BY MR. THOMAS:

19 Q. The only other case it could be
20 would be the Bellow case?

21 MR. ORENT: The doctor has not
22 testified previously about these issues. I don't
23 know whether or not there has been another report
24 on another matter disclosed.

25 It may very well be that there is

1 something that's still work product and not been
2 disclosed. So I don't want to get into the details
3 of that other potential matter.

4 BY MR. THOMAS:

5 Q. Let me just ask it this way: The
6 bills that you've submitted to counsel in this
7 matter do not reflect any charges for time that
8 you've spent reviewing Ethicon documents or
9 depositions, correct?

10 A. Partially, they do. I reviewed
11 some of that again; it's been drafted earlier.

12 MR. ORENT: Counsel, just to speed this
13 area up to the extent that it's not clear on the
14 bills, I think what we can do is we can supplement
15 by letter.

16 MR. THOMAS: That would be fine. I'm
17 not interested in getting anybody. I just want --

18 MR. ORENT: I think what we'll do is we
19 can figure out the amount of time.

20 MR. THOMAS: I just want to make sure
21 you get paid for your time. You have to send your
22 bills and get paid.

23 Okay, that's all the questions I have,
24 Doctor. Thank you.

25 THE WITNESS: Thank you.

1 MR. ORENT: Why don't we take two
2 minutes. I'll going to have probably about ten
3 minutes worth of questions.

4 -- RECESS TAKEN AT 4:52 --

5 -- UPON RESUMING AT 4:55 --

6 CROSS-EXAMINATION BY MR. ORENT:

7 Q. Good afternoon, Doctor.

8 A. Good afternoon.

9 Q. Earlier today you were asked a
10 number of questions about each of the
11 photomicrographs that we looked at, and one of the
12 predicate questions that you were asked for each
13 one was whether or not it was a TVT or a TVT-O; do
14 you recall being asked that series of questions?

15 A. Yes, I do.

16 Q. For purposes of your work does it
17 make any difference whether or not the product is
18 the TVT or TVT-O in terms of your findings as
19 reported here?

20 A. No, it's the same sling, the same
21 mesh. The only difference is how it's placed and
22 the other components which come in the kit.

23 Q. So if I understand your testimony,
24 is it your testimony that the TVT and the TVT-O --
25 the actual mesh device is the exact same?

1 A. Exactly the same.

2 Q. Okay. And so in terms of the
3 pathological findings that you make, as reported in
4 your report and your supplement, is there a -- is
5 there any reason for making a distinction between
6 the two devices?

7 MR. THOMAS: Object to the form of the
8 question.

9 THE WITNESS: No. The only difference
10 is there can be more frequent occurrences of
11 striated muscle in the TVT-O samples than in TVT,
12 but it can be seen in both.

13 BY MR. ORENT:

14 Q. And is that because of the
15 implantation route?

16 A. That's correct.

17 Q. And both devices are made of
18 Prolene mesh; is that correct?

19 A. That is correct.

20 Q. Now every one of the
21 photomicrographs that appear in Exhibits 1 and 2 to
22 today's deposition, that is your report and
23 supplemental report, did every one of those
24 photomicrographs appear either from prior expert
25 reports in Ethicon litigation, in the specific

1 pathology of the consolidated plaintiffs, or in
2 peer-reviewed medical literature written by you?

3 A. That's correct. These are the
4 three sources.

5 Q. And you've been asked questions
6 today about identifying various -- what you called
7 additional TVT cases in your report; do you recall
8 those questions?

9 A. Yes, I do.

10 Q. Did you produce photomicrographs
11 of the additional TVT cases in the course of other
12 reports you've provided in TVT cases?

13 A. Yes, I did.

14 Q. Now, with regard to the opinions
15 that you express in your expert report in this
16 case, and your supplement, do you use the same
17 methodology that you have previously used when you
18 testified in the western district -- excuse me, in
19 the southern district of West Virginia?

20 A. Yes, exactly the same methodology.

21 Q. And is your -- the materials and
22 your methodology that you utilized in this report
23 the same methodology that you've used in other
24 courts where you have been allowed to testify at
25 trial?

1 A. That's correct.

2 Q. Did you use any different
3 techniques in this report?

4 A. No.

5 Q. Okay. Now, the opinions that you
6 testified to in this report, and in the supplement,
7 are they identical to the opinions that you've
8 previously provided in trial in matters before the
9 southern district of West Virginia?

10 A. Yes.

11 MR. THOMAS: Object to form.

12 THE WITNESS: That is correct. The
13 same opinions.

14 BY MR. ORENT:

15 Q. Are they, the opinions that you
16 express in your expert report and in the
17 supplement, are they also identical to opinions
18 that you have provided in other courts during
19 trials throughout the country?

20 MR. THOMAS: Object to form.

21 THE WITNESS: That is correct.

22 BY MR. ORENT:

23 Q. And throughout the course of your
24 report you provide just a few examples of a variety
25 of failure modes associated with the TVT and TVT-O

1 device; is that correct?

2 MR. THOMAS: Object to form.

3 THE WITNESS: That is correct.

4 BY MR. ORENT:

5 Q. And why is it that you don't list
6 a sample size or rate of error in your report?

7 A. It's not the purpose. I'm not
8 analyzing statistically frequency or rate of
9 occurrence. I showed the changes which can occur.
10 It's binary assessment; either it can occur or
11 cannot occur. It can occur in one case, it can
12 occur in 100 percent of cases, but it can happen.
13 For a specific patient it either occurs or it
14 doesn't.

15 Q. In order to show that something
16 can occur, in terms of a failure mode, is there a
17 sample size, a minimum sample size that you have
18 need to show that a failure rate or failure mode
19 can occur?

20 MR. THOMAS: Object to form.

21 THE WITNESS: One case is enough. If
22 it can occur in one case, it can occur again.

23 BY MR. ORENT:

24 Q. And these concepts of sample size
25 with one being enough to prove capability, is that

1 something that's generally accepted in the medical
2 community, in the scientific community?

3 MR. THOMAS: Object to form.

4 THE WITNESS: Yes. If you answer the
5 question if it can occur, one case is enough.

6 BY MR. ORENT:

7 Q. Same thing with a binary
8 observation; it either occurs or doesn't occur.
9 There's no rate of error associated with that; is
10 that correct?

11 MR. THOMAS: Object to the form of the
12 question.

13 THE WITNESS: It's either there or it's
14 not. It's either zero occurrence or 100 percent.

15 BY MR. ORENT:

16 Q. When you talk about using large
17 enough sample sizes and large enough rates of
18 error, is that only used when you actually try and
19 extrapolate from a data set to an individual?

20 MR. THOMAS: Object to the form of the
21 question.

22 THE WITNESS: That's used to predict
23 specific rates of specific occurrence, and that's
24 used in relation to a cohort of patients and
25 devices. And it's a different question.

1 BY MR. ORENT:

2 Q. Okay. And in terms of the
3 opinions that you provided here in your expert
4 report, do you hold each of those opinions to a
5 reasonable degree of medical and professional
6 certainty?

7 A. Yes, I do.

8 Q. And with regard to the various
9 staining techniques that you've utilized, are each
10 one of those staining techniques peer-reviewed in
11 their own right?

12 MR. THOMAS: Object to the form of the
13 question.

14 THE WITNESS: That is correct, yes.

15 BY MR. ORENT:

16 Q. Has H&E been utilized as a stain
17 and been peer-reviewed as a proper way of looking
18 at tissue for a significant period of time?

19 A. Over 100 years, or over the course
20 of 100 years.

21 Q. How about myeloperoxidase, has
22 that been peer-reviewed as use for staining?

23 MR. THOMAS: Object to the form of the
24 question.

25 THE WITNESS: We have several decades

1 of use.

2 BY MR. ORENT:

3 Q. And how about S100?

4 MR. THOMAS: Object to the form of the
5 question.

6 THE WITNESS: Same thing. It's been
7 used since late '70s, early '80s.

8 BY MR. ORENT:

9 Q. What about the use of polarizing
10 light, is that something that's peer-reviewed and
11 accepted in the identification of crystalline
12 substances?

13 A. It's been described for histology
14 use from 1920s, and even I saw it's been used in
15 Ethicon studies as well. Ethicon scientists were
16 using polarized light as well. Well, let me
17 rephrase that. Who came to the same conclusions I
18 came.

19 Q. And with regard to the medical
20 peer-reviewed literature on mesh and mesh
21 complications, in fact, there's a group out of the
22 University of Michigan that published utilizing
23 some of the same techniques that you've described
24 in your report; is that correct?

25 MR. THOMAS: Object to the form of the

1 question.

2 THE WITNESS: Yes.

3 BY MR. ORENT:

4 Q. Now, with regard to the work that
5 you've done here, none of these opinions are new;
6 is that right?

7 MR. THOMAS: Object to the form of the
8 question.

9 THE WITNESS: That is correct.

10 BY MR. ORENT:

11 Q. And in terms of the material that
12 you've produced on disk. Having provided to
13 counsel today, did you produce all non-confidential
14 materials that you could provide?

15 A. Yes. I selected that I could
16 safely release.

17 Q. You were also asked a number of
18 questions about the peer review and peer-review
19 process; do you recall those questions?

20 A. Yes, I do.

21 Q. As an academic, do you have
22 concerns about maintaining the integrity of the
23 peer-review process?

24 A. Could you repeat the question.

25 Q. Sure. As an academic, as an

1 author and a researcher, are there important
2 reasons why the confidentiality of the
3 peer-review process needs to be maintained?

4 A. Yes. I mean, especially when
5 there is an involvement of a manufacturer, because
6 I mean, this is major concern.

7 Most publications -- journals, they
8 require, the first thing they need to have
9 submitted, has it been funded by industry, by
10 manufacturers. So it's a major concern to try to
11 be independent from manufacturers.

12 MR. ORENT: All right, Doctor, thank
13 you very much. I have no further questions.

14 MR. THOMAS: Thank you, Doctor, for
15 your time.

16

17

18 -- Whereupon the deposition concluded at 5:05 p.m.

19

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25

REPORTER'S CERTIFICATE

I, JUDITH M. CAPUTO, RPR, CSR, CRR,
Registered Professional Reporter, certify;

That the foregoing proceedings were
taken before me at the time and place therein set
forth, at which time the witness was put under oath
by me;

That the testimony of the witness and
all objections made at the time of the examination
were recorded stenographically by me and were
thereafter transcribed;

That the foregoing is a true and
correct transcript of my shorthand notes so taken.

Dated this 14th day of September, 2015.

PER: JUDITH CAPUTO, RPR, CSR, CRR

1 CERTIFICATE OF REPORTER

2 CANADA)

3 PROVINCE OF ONTARIO)

4

5 I, Judith M. Caputo, the officer before whom the
6 foregoing deposition was taken, do hereby certify
7 that the witness whose testimony appears in the
8 foregoing deposition was duly sworn by me; that the
9 testimony of said witness was taken by me in
10 shorthand, using Computer Aided Realtime, to the
11 best of my ability and thereafter reduced to
12 written format under my direction; that I am
13 neither counsel for, related to, nor employed by
14 any of the parties to the action in which the
15 deposition was taken, and further that I am not
16 related or any employee of any attorney or counsel
17 employed by the parties thereto, nor financially or
18 otherwise interested in the outcome of the action.

19

20

21 _____

22 Judith M. Caputo, RPR, CSR, CRR

23

24 Commissioner for taking

25 Oaths in the Province of Ontario

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2

3 Read your deposition over carefully.

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7 sheet for any change made.

8 After making any changes in form or
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13 Then sign your deposition at the end of
14 Your testimony in the space provided. You are
15 signing it subject to the changes you have made in
16 the erratum sheet, which will be attached to the
17 deposition before filing. You must sign it in
18 front of a witness. The witness need not be a
19 notary public. Any competent adult may witness
20 your signature.

21 Return the original erratum sheet
22 promptly. Court rules require filing within 30
23 days after you receive the deposition.

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25

1 * * ERRATA SHEET * *

2

3 NAME OF CASE: TERRESKI MULLINS, ET AL. V.

4 ETHICON, INC., ET AL.

5 DATE OF DEPOSITION: SEPTEMBER 14th, 2015

6 NAME OF WITNESS: VLADIMIR IAKOVLEV

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25 VLADIMIR IAKOVLEV

1 PROVINCE OF ONTARIO)

2 TORONTO REGION)

3

4

5 I, the undersigned, declare under
6 penalty of perjury that I have read the foregoing
7 transcript, and I have made any corrections,
8 additions or deletions that I was desirous of
9 making;

10 That the foregoing is a true and
11 correct transcript of my testimony contained
12 therein.

13

14

15 _____
VLADIMIR IAKOVLEV, M.D.

16

17

18 Subscribed and sworn to before me this ____

19 Day of _____, 2015 at

20 _____, _____.

21 (City) (Province)

22

23

24 (Notary Public)

25 My Commission Expires: _____